Horizon Pharma plc
Form 10-Q
November 07, 2016

UNITED STATES

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, 2016

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 (State or other jurisdiction	Not Applicable (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, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting 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

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 November 2, 2016: 161,257,419.

HORIZON PHARMA PLC

INDEX

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

HORIZON PHARMA PLC

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share data)

	As of September 30, 2016	As of December 31, 2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$549,303	$859,616
Restricted cash	5,271	1,860
Accounts receivable, net	362,899	210,437
Inventories, net	162,155	18,376
Prepaid expenses and other current assets	38,078	15,858
Total current assets	1,117,706	1,106,147
Property and equipment, net	21,442	14,020
Developed technology, net	1,877,158	1,609,049
In-process research and development	66,000	66,000
Other intangible assets, net	6,453	7,061
Goodwill	248,736	253,811
Deferred tax assets, net	5,975	2,278
Other assets	6,201	222
TOTAL ASSETS	$3,349,671	$3,058,588
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Long-term debt—current portion	$4,000	$4,000
Accounts payable	65,684	16,590
Accrued expenses	157,534	100,046
Accrued trade discounts and rebates	268,202	183,769
Accrued royalties—current portion	59,176	51,700
Deferred revenues—current portion	1,635	1,447
Total current liabilities	556,231	357,552
LONG-TERM LIABILITIES:		
Exchangeable notes, net	294,089	282,889
Long-term debt, net, net of current	849,135	849,867
Accrued royalties, net of current	169,618	123,519
Deferred revenues, net of current	8,154	8,785
Deferred tax liabilities, net	95,583	113,400

Other long-term liabilities	14,883	9,431
Total long-term liabilities	1,431,462	1,387,891
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares, $0.0001 nominal value; 300,000,000 shares authorized; 161,618,473 and 160,069,067 shares issued at September 30, 2016 and December 31, 2015, respectively, and 161,234,107 and 159,684,701 shares outstanding at September 30, 2016 and December 31, 2015, respectively	16	16
Treasury stock, 384,366 ordinary shares at September 30, 2016 and December 31, 2015	(4,585)	(4,585)
Additional paid-in capital	2,086,873	2,001,552
Accumulated other comprehensive loss	(2,847)	(2,651)
Accumulated deficit	(717,479)	(681,187)
Total shareholders' equity	1,361,978	1,313,145
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$3,349,671	$3,058,588

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 September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
Net sales	$208,702	$226,544	$670,770	$512,506
Cost of goods sold	85,161	61,250	243,520	151,929
Gross profit	123,541	165,294	427,250	360,577
OPERATING EXPENSES:				
Research and development	12,814	13,073	36,746	28,176
Sales and marketing	72,564	51,973	227,697	157,092
General and administrative	59,485	54,516	179,866	157,986
Total operating expenses	144,863	119,562	444,309	343,254
Operating (loss) income	(21,322)	45,732	(17,059)	17,323
OTHER INCOME (EXPENSE), NET:				
Interest expense, net	(19,066)	(20,300)	(57,752)	(49,780)
Foreign exchange loss	(108)	(86)	(266)	(1,010)
Loss on induced conversion of debt and debt extinguishment	—	—	—	(77,624)
Other income (expense), net	6,879	(90)	6,839	(10,159)
Total other income (expense), net	(12,295)	(20,476)	(51,179)	(138,573)
(Loss) income before (benefit) expense for income taxes	(33,617)	25,256	(68,238)	(121,250)
(BENEFIT) EXPENSE FOR INCOME TAXES	(27,747)	21,979	(31,946)	(136,788)
NET (LOSS) INCOME	$(5,870)	$3,277	$(36,292)	$15,538
NET (LOSS) INCOME PER ORDINARY SHARE—Basic	$(0.04)	$0.02	$(0.23)	$0.11
WEIGHTED AVERAGE ORDINARY SHARES OUTSTANDING—Basic	161,038,827	159,035,580	160,472,530	145,208,252
NET (LOSS) INCOME PER ORDINARY SHARE—Diluted	$(0.04)	$0.02	$(0.23)	$0.10
WEIGHTED AVERAGE ORDINARY SHARES OUTSTANDING—Diluted	161,038,827	166,830,800	160,472,530	154,005,671
OTHER COMPREHENSIVE LOSS, NET OF TAX				
Foreign currency translation adjustments	(110)	(48)	(196)	1,559
Unrealized loss on long-term investment	—	(29,400)	—	(29,400)
Other comprehensive loss	(110)	(29,448)	(196)	(27,841)
COMPREHENSIVE LOSS	$(5,980)	$(26,171)	$(36,488)	$(12,303)

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 Months Ended September 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income	$(36,292)	$15,538
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization expense	154,465	94,025
Equity-settled share-based compensation	84,011	56,253
Royalty accretion	28,762	13,571
Royalty liability remeasurement	—	14,277
Loss on induced conversions of debt and debt extinguishment	—	21,581
Amortization of debt discount and deferred financing costs	13,469	13,328
Deferred income taxes	(35,158)	(134,014)
Foreign exchange loss and other adjustments	268	1,137
Changes in operating assets and liabilities:		
Accounts receivable	(142,448)	(135,370)
Inventories	23,842	12,819
Prepaid expenses and other current assets	(20,838)	417
Accounts payable	49,695	38,213
Accrued trade discounts and rebates	83,009	35,136
Accrued expenses and accrued royalties	29,582	11,052
Deferred revenues	(443)	2,143
Payment of original issue discount upon repayment of 2014 Term Loan Facility	—	(3,000)
Other non-current assets and liabilities	(1,653)	2,122
Net cash provided by operating activities	230,271	59,228
CASH FLOWS FROM INVESTING ACTIVITIES:		
Payments for acquisitions, net of cash acquired	(520,405)	(1,022,361)
Proceeds from the liquidation of available-for-sale investments	—	64,623
Purchases of long-term investments	—	(71,813)
Purchases of property and equipment	(14,616)	(4,514)
Change in restricted cash	(3,411)	(122)
Net cash used in investing activities	(538,432)	(1,034,187)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of Exchangeable Senior Notes	—	387,181
Net proceeds from issuance of 2023 Senior Notes	—	462,340
Net proceeds from the 2015 Term Loan Facility	—	391,506
Repayment of the 2014 Term Loan Facility	—	(297,000)

Repayment of the 2015 Term Loan Facility	(3,000)	(1,000)
Net proceeds from the issuance of ordinary shares	—	475,627
Proceeds from the issuance of ordinary shares in connection with warrant exercises	—	18,124
Proceeds from the issuance of ordinary shares through ESPP programs	3,235	1,541
Proceeds from the issuance of ordinary shares in connection with stock option exercises	3,384	4,602
Payment of employee withholding taxes relating to share-based awards	(5,309)	(2,334)
Net cash (used in) provided by financing activities	(1,690)	1,440,587
Effect of foreign exchange rate changes on cash	(462)	(149)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(310,313)	465,479
CASH AND CASH EQUIVALENTS, beginning of the period	859,616	218,807
CASH AND CASH EQUIVALENTS, end of the period	$549,303	$684,286

	For the Nine Months Ended September 30,	
	2016	2015
Supplemental cash flow information:		
Cash paid for interest	$39,542	$21,417
Cash paid for income taxes	18,538	1,903
Fee paid for debt commitment	—	9,000
Cash paid for induced conversions	—	10,005
Cash paid for debt extinguishment	—	45,367
Supplemental non-cash flow information:		
Conversion of Convertible Senior Notes to ordinary shares	$—	$60,985
Purchases of property and equipment included in accounts payable and accrued expenses	1,101	1,130

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, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. The December 31, 2015 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by GAAP.

On September 19, 2014, the businesses of Horizon Pharma, Inc. ("HPI") and Vidara Therapeutics International Public Limited Company ("Vidara") were combined in a merger transaction (the "Vidara Merger"), accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with HPI treated as the acquiring company in the Vidara Merger for accounting purposes. As part of the Vidara Merger, a wholly owned subsidiary of Vidara merged with and into HPI, with HPI surviving the Vidara Merger as a wholly owned subsidiary of Vidara. Prior to the Vidara Merger, Vidara changed its name to Horizon Pharma plc (the "Company"). Upon the consummation of the Vidara Merger, the historical financial statements of HPI became the Company's historical financial statements.

On May 7, 2015, the Company completed its acquisition of Hyperion Therapeutics Inc. ("Hyperion") in which the Company acquired all of the issued and outstanding shares of Hyperion's common stock for $46.00 per share in cash, or approximately $1.1 billion on a fully-diluted basis. Following completion of the acquisition, Hyperion became a wholly owned subsidiary of the Company and was renamed as Horizon Therapeutics, Inc.

On January 13, 2016, the Company completed its acquisition of Crealta Holdings LLC ("Crealta") for approximately $539.7 million, including cash acquired of $24.9 million. Following completion of the acquisition, Crealta became a wholly owned subsidiary of the Company and was renamed as Horizon Pharma Rheumatology LLC.

The unaudited condensed consolidated financial statements presented herein include the results of operations of the acquired Hyperion and Crealta businesses from the applicable dates of acquisition. See Note 3 for further details of business acquisitions.

On May 18, 2016, the Company entered into a definitive agreement with Boehringer Ingelheim International GmbH ("Boehringer Ingelheim International") to acquire certain rights to interferon gamma-1b, which Boehringer Ingelheim International currently commercializes under the trade names IMUKIN®, IMUKINE®, IMMUKIN® and IMMUKINE® in an estimated 30 countries, primarily in Europe and the Middle East. Under the terms of the agreement, the Company paid Boehringer Ingelheim International €5.0 million ($5.6 million when converted using a Euro-to-Dollar exchange rate of 1.1132) upon signing and will pay €20.0 million upon closing, for certain rights for

interferon gamma-1b in all territories outside of the United States, Canada and Japan, as the Company currently holds marketing rights to interferon gamma-1b in these territories. The Company currently markets interferon gamma-1b as ACTIMMUNE® in the United States. The transaction is expected to close in the first half of 2017 and the Company is continuing to work with Boehringer Ingelheim International to enable the transfer of applicable marketing authorizations. Under the terms of a separate agreement, the Company also in-licensed certain U.S., European and Canadian intellectual property rights for interferon gamma-1b for the treatment of Friedreich's ataxia ("FA"). Interferon gamma-1b is currently not indicated or approved for the treatment of FA.

On October 25, 2016, the Company completed its acquisition of Raptor Pharmaceutical Corp. ("Raptor") in which the Company acquired all of the issued and outstanding shares of Raptor's common stock for $9.00 per share in cash, or approximately $804.7 million on a fully-diluted basis. Following completion of the acquisition, Raptor became a wholly owned subsidiary of the Company and converted to a Delaware limited liability company, changing its name to Horizon Pharmaceutical LLC. The Company financed the transaction through $300.0 million aggregate principal amount of 8.75% Senior Notes due 2024 (the "2024 Senior Notes"), $375.0 million aggregate principal amount of loans pursuant to an amendment to the Company's existing credit agreement and cash on hand. See Note 18 for additional details.

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, including its predecessor, HPI. All references to "Vidara" are references to Horizon Pharma plc (formerly known as Vidara Therapeutics International Public Limited Company) and its consolidated subsidiaries prior to the effective time of the Vidara Merger on September 19, 2014.

The unaudited condensed consolidated financial statements presented herein include the accounts of the Company and its wholly owned subsidiaries. All inter-company transactions and balances have been eliminated.

Business Overview

The Company is a biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs. The Company markets eleven medicines through its orphan, rheumatology and primary care business units. The Company's marketed medicines are ACTIMMUNE® (interferon gamma-1b), BUPHENYL® (sodium phenylbutyrate) Tablets and Powder, DUEXIS® (ibuprofen/famotidine), KRYSTEXXA® (pegloticase), MIGERGOT® (ergotamine tartrate & caffeine suppositories), PENNSAID® (diclofenac sodium topical solution) 2% w/w ("PENNSAID 2%"), PROCYSBI® (cysteamine bitartrate) delayed-release capsules, QUINSAIR™ (aerosolized form of levofloxacin), RAVICTI® (glycerol phenylbutyrate) Oral Liquid, RAYOS® (prednisone) delayed-release tablets and VIMOVO® (naproxen/esomeprazole magnesium).

The Company developed DUEXIS and RAYOS, known as LODOTRA® outside the United States, acquired the U.S. rights to VIMOVO from AstraZeneca AB ("AstraZeneca") in November 2013, acquired certain rights to ACTIMMUNE as a result of the Vidara Merger in September 2014, acquired the U.S. rights to PENNSAID 2% from Nuvo Research Inc. ("Nuvo") in October 2014, acquired RAVICTI and BUPHENYL, known as AMMONAPS®, in certain European countries, as a result of the acquisition of Hyperion in May 2015, acquired KRYSTEXXA and the U.S. rights to MIGERGOT as a result of the acquisition of Crealta in January 2016 and acquired PROCYSBI and QUINSAIR as a result of the acquisition of Raptor in October 2016.

The Company's medicines are dispensed by retail and specialty pharmacies. Part of the Company's commercial strategy for its primary care and rheumatology business units is to offer physicians the opportunity to have their patients fill prescriptions through pharmacies participating in the Company's HorizonCares patient access program. This program does not involve the Company in the prescribing of medicines. The purpose of this program is solely to assist in ensuring that, when physicians determine that one of the Company's medicines offers a potential clinical benefit to their patients and prescribe the medicine for an eligible patient, financial assistance may be available to reduce a commercial patient's out-of-pocket costs. In the first nine months of 2016, this resulted in 99.9 percent of commercial patients having co-pay amounts of $10 or less when filling prescriptions for the Company's medicines utilizing its patient access program. For commercial patients who are prescribed the Company's primary care medicines or RAYOS, the HorizonCares program offers co-pay assistance when a third-party payer covers a prescription but requires an eligible patient to pay a co-pay or deductible, and offers full subsidization when a third-party payer rejects coverage for an eligible patient. For patients who are prescribed the Company's orphan medicines, the Company's patient access programs provide reimbursement support, a clinical nurse program, co-pay and other patient assistance. The aggregate commercial value of the Company's patient access programs for the nine months ended September 30, 2016 was $1,275.2 million. All pharmacies that dispense prescriptions for the Company's medicines, which the Company estimates to be about 20,000 during the first nine months of 2016, are fully independent, including those that participate in HorizonCares. The Company does not own or possess any option to purchase an ownership stake in any pharmacy that distributes its medicines, and the Company's relationship with each pharmacy is non-exclusive and arm's length. All of the Company's medicines are dispensed through pharmacies independent of its business.

As an alternative means of ensuring access to its medicines, the Company has also begun pursuing business arrangements with pharmacy benefit managers ("PBMs") and other payers to secure formulary status and reimbursement of the Company's medicines, such as the Company's recently announced arrangements with CVS Caremark and Prime Therapeutics LLC. While the Company believes that, if successful, this strategy would result in broader inclusion of certain of the Company's primary care medicines on healthcare plan formularies, and therefore increase payer reimbursement and lower the Company's cost of providing patient access programs, these arrangements generally require the Company to pay administrative and rebate payments to the PBMs and/or other payers.

The Company has a compliance program in place to address adherence with various laws and regulations relating to the selling, marketing and manufacturing of the Company's medicines, as well as certain third-party relationships, including pharmacies. Specifically with respect to pharmacies, the compliance program utilizes a variety of methods and tools to monitor and audit pharmacies, including those that participate in the Company's patient access programs, to confirm their activities, adjudication and practices are consistent with the Company's compliance policies and guidance.

The Company markets its medicines in the United States through its field sales force, which numbered approximately 470 representatives as of September 30, 2016. The Company's strategy is to use the commercial strength and infrastructure it has established in creating a global biopharmaceutical company to continue the successful commercialization of the Company's existing medicine portfolio while also expanding and leveraging these capabilities by identifying, developing, acquiring and commercializing additional differentiated and accessible medicines that address unmet medical needs.

The Company is a public limited company formed under the laws of Ireland. The Company operates through a number of international and U.S. subsidiaries with principal business purposes to either perform research and development or manufacturing operations, serve as distributors of the Company's medicines, hold intellectual property assets or provide services and financial support to the Company.

Recent Accounting Pronouncements

From time to time, the Company adopts, as of the specified effective date, new accounting pronouncements issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Subtopic 606). 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 retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. In March 2016 and April 2016, the FASB issued ASU No. 2016-08 and ASU No. 2016-10, respectively, which further clarify the implementation guidance on principal versus agent considerations contained in ASU No. 2014-09. In May 2016, the FASB issued ASU 2016-12, narrow-scope improvements and practical expedients which provides clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition. These standards will be effective for the Company beginning in the first quarter of 2018. Early adoption is permitted, but not before December 15, 2016, the original effective date of the standard. The Company has not yet selected a transition method nor has it determined the impact of the new standard on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU No. 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). ASU No. 2014-15 provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations in the financial statement footnotes. ASU No. 2014-15 is effective for annual reporting periods ending after December 15, 2016 and to annual and interim periods thereafter. Early adoption is permitted. The Company adopted ASU No. 2014-15 on April 1, 2016, and the adoption did not have a material impact on the consolidated financial statements and related disclosures.

In April 2015, the FASB issued ASU No. 2015-03, Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. In August 2015, the FASB issued ASU No. 2015-15, which further clarifies the implementation guidance of ASU No. 2015-03. The amendments in these ASUs are effective for the financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The Company adopted ASU No. 2015-03 on January 1, 2016. The following table summarizes the adjustments made to conform prior period classifications as a result of the new guidance (in thousands):

	As of December 31, 2015		
	As filed	Reclassification	As adjusted
Other non-current assets	$8,581	$ (8,359)	$222
Exchangeable notes, net	(283,675)	786	(282,889)
Long-term debt, net, net of current	(857,440)	7,573	(849,867)

In April 2015, the FASB issued ASU No. 2015-05: Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement which provides guidance on a customer's accounting for fees paid in a cloud computing arrangement. Under the new standard, customers will apply the same criteria as vendors to determine whether a cloud computing arrangement contains a software license or is solely a service contract. The amendments in this ASU, which may be applied prospectively or retrospectively, are effective for annual and interim periods beginning after December 15, 2015. The Company adopted ASU No. 2015-05 on January 1, 2016 and the adoption did not have a material impact on the consolidated financial statements and related disclosures.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Under this new guidance, entities that measure inventory using any method other than last-in, first-out or the retail inventory method will be required to measure inventory at the lower of cost and net realizable value. The amendments in this ASU, which should be applied prospectively, are effective for annual and interim periods beginning after December 15, 2016. Early adoption is permitted. The Company adopted ASU No. 2015-11 on April 1, 2016, and the adoption did not have a material impact on the consolidated financial statements and related disclosures.

In September 2015, the FASB issued ASU No. 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments ("ASC 805"). Under this guidance, an acquirer is required to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments in this ASU require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The amendments in this ASU require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. The amendments in this ASU, which should be applied prospectively, are effective for annual and interim periods beginning after December 15, 2015. The Company adopted ASU No. 2015-16 on January 1, 2016, and the adoption did not have a material impact on the consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). 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. At adoption, this update will be applied using a modified retrospective approach. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2016-02 on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The updated guidance will change how companies account for certain aspects of share-based payments to employees. Entities will be required to recognize the income tax effects of awards in the statement of income when the awards vest or are settled. The guidance on accounting for an employee's use of shares to satisfy the statutory income tax withholding obligation and for forfeitures is changing, and the update requires companies to present excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. The amendments in this update will be effective for annual periods beginning after December 15, 2016 and interim periods within those annual periods. Early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2016-09 on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic230): Classification of Certain Cash Receipts and Cash Payments. The amendments in this ASU provide 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. Current GAAP does not include specific guidance on these eight cash flow classification issues. The amendments of this ASU are effective for reporting periods beginning after December 15, 2017, with early adoption permitted. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2016-15 on its consolidated financial statements and related disclosures.

NOTE 2 – NET (LOSS) INCOME PER SHARE

The following table presents basic net (loss) income per share for the three and nine months ended September 30, 2016 and 2015 (in thousands, except share and per share data):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
Basic net (loss) income per share calculation:				
Net (loss) income	$ (5,870)	$ 3,277	$ (36,292)	$ 15,538
Weighted average ordinary shares outstanding	161,038,827	159,035,580	160,472,530	145,208,252
Basic net (loss) income per share	$ (0.04)	$ 0.02	$ (0.23)	$ 0.11

The following table presents diluted net (loss) income per share for the three and nine months ended September 30, 2016 and 2015 (in thousands, except share and per share data):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
Diluted net (loss) income per share calculation:				
Net (loss) income	$ (5,870)	$ 3,277	$ (36,292)	$ 15,538
Weighted average ordinary shares outstanding	161,038,827	166,830,800	160,472,530	154,005,671
Diluted net (loss) income per share	$ (0.04)	$ 0.02	$ (0.23)	$ 0.10

Basic net (loss) income per share is computed by dividing net (loss) income by the weighted-average number of ordinary shares outstanding during the period. Diluted net income per share reflects the potential dilution beyond shares for basic net income per share 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) income per share excluded 11.6 million and 14.2 million equity awards for the three and nine months ended September 30, 2016, respectively, and 5.6 million and 4.4 million equity awards for the three and nine months ended September 30, 2015, respectively, because their inclusion would have had an anti-dilutive effect on diluted net (loss) income 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. The calculated spread added to the denominator for the three and nine months ended September 30, 2015 was 1,298,616 and 775,807 ordinary shares, respectively. There was no calculated spread added to the denominator for the three and nine months ended September 30, 2016.

NOTE 3 – BUSINESS ACQUISITIONS

Raptor Acquisition

On October 25, 2016, the Company completed its acquisition of Raptor in which the Company acquired all of the issued and outstanding shares of Raptor's common stock for $9.00 per share in cash or approximately $804.7 million on a fully-diluted basis. The acquisition added two medicines, PROCYSBI and QUINSAIR, to the Company's medicine portfolio. Through the acquisition, the Company expects to leverage as well as expand the existing infrastructure of its orphan disease business. Following completion of the acquisition, Raptor became a wholly owned subsidiary of the Company and converted to a Delaware limited liability company, changing its name to Horizon Pharmaceutical LLC. The Company financed the transaction through $300.0 million of aggregate principal amount of 2024 Senior Notes, $375.0 million aggregate principal amount of loans pursuant to an amendment to the Company's existing credit agreement and cash on hand. See Note 18 for additional details.

Acquisition of Additional Rights to Interferon Gamma-1b

On May 18, 2016, the Company entered into a definitive agreement with Boehringer Ingelheim International to acquire certain rights to interferon gamma-1b, which Boehringer Ingelheim International currently commercializes under the trade names IMUKIN, IMUKINE, IMMUKIN and IMMUKINE in an estimated 30 countries primarily in Europe and the Middle East. Under the terms of the agreement, the Company paid Boehringer Ingelheim International €5.0 million ($5.6 million when converted using a Euro-to-Dollar exchange rate of 1.1132) upon signing and will pay €20.0 million upon closing, for certain rights for interferon gamma-1b in all territories outside of the United States, Canada and Japan, as the Company currently holds marketing rights to interferon gamma-1b in these territories. The transaction is expected to close in the first half of 2017 and the Company is continuing to work with Boehringer Ingelheim International to enable the transfer of applicable marketing authorizations. The Company currently markets interferon gamma-1b as ACTIMMUNE in the United States. The €5.0 million ($5.6 million) upfront amount paid in May 2016 has been included in "other assets" in the Company's condensed consolidated balance sheet as of September 30, 2016.

Crealta Acquisition

On January 13, 2016, the Company completed its acquisition of all the membership interests of Crealta. The acquisition added two medicines, KRYSTEXXA and MIGERGOT, to the Company's medicine portfolio. The Crealta acquisition further diversified the Company's portfolio of medicines and aligned with its focus of acquiring value-enhancing, clinically differentiated, long-life medicines that treat orphan diseases. The total consideration for the acquisition was approximately $539.7 million, including cash acquired of $24.9 million, and was composed of the following before and after the measurement period adjustments (in thousands):

	Before	Adjustments	After
Cash	$536,181	$ 25	$536,206
Net settlements on the exercise of stock options and unrestricted units	3,526	—	3,526
Total consideration	$539,707	$ 25	$539,732

During the three and nine months ended September 30, 2016, the Company incurred $0.4 million and $12.1 million, respectively, in Crealta acquisition-related costs including advisory, legal, accounting, valuation, severance, retention bonuses and other professional and consulting fees. During the three and nine months ended September 30, 2016, $0.5 million and $11.5 million were accounted for as "general and administrative", respectively, a net expense reduction of $0.1 million and a net expense of $0.2 million were accounted for as "research and development", respectively, and zero and $0.4 million were accounted for as "costs of goods sold", respectively, in the condensed consolidated statements of comprehensive loss.

Pursuant to ASC 805, the Company accounted for the Crealta acquisition as a business combination using the acquisition method of accounting. Identifiable assets and liabilities of Crealta, including identifiable intangible assets, were recorded based on their estimated fair values as of the date of the closing of the acquisition. The excess of the purchase price over the fair value of the net assets acquired was recorded as goodwill. Significant judgment was required in determining the estimated fair values of developed technology intangible assets, inventories and certain other assets and liabilities. Such preliminary valuation required estimates and assumptions including, but not limited to, estimating future cash flows and direct costs in addition to developing the appropriate discount rates and current market profit margins. The Company's management believes the fair values recognized for the assets acquired and the liabilities assumed are based on reasonable estimates and assumptions. Accordingly, the unaudited purchase price adjustments are preliminary and are subject to further adjustments as additional information becomes available and as additional analyses are performed, and such further adjustments may be material.

During the nine months ended September 30, 2016, the Company recorded measurement period adjustments related to developed technology and inventory, which resulted in a net increase in goodwill of $0.3 million. The measurement period adjustments were the result of a net working capital true-up adjustment and the alignment of Crealta's inventory and obsolescence reserve policy to the Company's policy.

The following table summarizes the preliminary fair values assigned to the assets acquired and the liabilities assumed by the Company, along with the resulting goodwill before and after the measurement period adjustments (in thousands):

(Liabilities assumed) and assets acquired:	Before	Adjustments	After
Accounts payable and accrued expenses	$(4,543)	$ —	$(4,543)
Accrued trade discounts and rebates	(1,424)	—	(1,424)
Deferred tax liabilities	(20,835)	—	(20,835)
Other non-current liabilities	(6,900)	—	(6,900)
Contingent royalty liabilities	(51,300)	—	(51,300)
Cash and cash equivalents	24,893	—	24,893
Accounts receivable	10,014	—	10,014
Inventories	169,054	(1,700)	167,354
Prepaid expenses and other current assets	1,382	—	1,382
Developed technology	417,300	1,400	418,700
Other non-current assets	275	—	275
Goodwill	1,791	325	2,116
Fair value of consideration paid	$539,707	$ 25	$539,732

Inventories acquired included raw materials, work in process and finished goods for KRYSTEXXA and MIGERGOT. Inventories were recorded at their preliminary estimated fair values. The fair value of finished goods has been determined based on the estimated selling price, net of selling costs and a margin on the selling costs. The fair value of work in process has been determined based on estimated selling price, net of selling costs and costs to complete the manufacturing, and a margin on the selling and manufacturing costs. The fair value of raw materials was estimated to equal the replacement cost. A step up in the value of inventory of $163.6 million was originally recorded in connection with the acquisition and this was reduced to $161.9 million following the recording of $1.7 million in measurement period adjustments during the nine months ended September 30, 2016. During the three and nine months ended September 30, 2016, the Company amortized inventory step-up of $11.3 million and $27.9 million, respectively.

Other tangible assets and liabilities were valued at their respective carrying amounts as management believes that these amounts approximated their acquisition date fair values.

Other non-current liabilities represented an assumed $6.9 million probable contingent liability which was released to “Other income (expense)” in the condensed consolidated statement of comprehensive loss during the three months ended September 30, 2016. See Note 12 for further details.

Identifiable intangible assets and liabilities acquired include developed technology and contingent royalties. The preliminary estimated fair values of the developed technology and contingent royalties represent preliminary valuations performed with the assistance of an independent appraisal firm based on management’s estimates, forecasted financial information and reasonable and supportable assumptions.

Developed technology intangible assets reflect the estimated fair value of Crealta’s rights to its currently marketed medicines, KRYSTEXXA and MIGERGOT. The preliminary fair value of developed technology was determined using an income approach. The income approach explicitly recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on current sales projections and estimated direct costs for Crealta’s medicines. Indications of value were developed by discounting these benefits to their acquisition-date worth at a discount rate of 27% for KRYSTEXXA and 23% for MIGERGOT. The fair value of the KRYSTEXXA and MIGERGOT developed technologies were capitalized as of the Crealta acquisition date and are subsequently being amortized over approximately 12 and 10 years, respectively, which are the periods in which over 90% of the estimated cash flows are expected to be realized.

The Company has assigned a preliminary fair value of $51.3 million to a contingent liability for royalties potentially payable under previously existing agreements related to KRYSTEXXA and MIGERGOT. The royalties for KRYSTEXXA are payable under the terms of a license agreement with Duke University (“Duke”) and Mountain View Pharmaceuticals (“MVP”). See Note 12 for details of the percentages of royalties payable under such agreements. The initial fair value of this liability was determined using a discounted cash flow analysis incorporating the estimated future cash flows of royalty payments resulting from future sales. The discount rate used was the same as for the fair value of the developed technology.

The preliminary deferred tax liability recorded represents deferred tax liabilities assumed as part of the acquisition, net of deferred tax assets, related to net operating tax loss carryforwards of Crealta.

Goodwill represents the excess of the preliminary acquisition consideration over the estimated fair value of net assets acquired and was recorded in the condensed consolidated balance sheet as of the acquisition date. The Company does not expect any portion of this goodwill to be deductible for tax purposes.

Hyperion Acquisition

On May 7, 2015, the Company completed the acquisition of Hyperion in which it acquired all of the issued and outstanding shares of Hyperion's common stock for $46.00 per share. The acquisition added two important medicines, RAVICTI and BUPHENYL, to the Company's medicine portfolio. Through the acquisition, the Company leveraged as well as expanded the existing infrastructure of its orphan disease business. The total consideration for the acquisition was approximately $1.1 billion and was composed of the following (in thousands, except share and per share data):

Fully diluted equity value (21,425,909 shares at $46.00 per share)	$985,592
Net settlements on the exercise of stock options, restricted stock and performance stock units	89,806
Total consideration	$1,075,398

During the three and nine months ended September 30, 2016, the Company recorded a net expense reduction of $0.2 million and $0.5 million, respectively, in Hyperion acquisition-related costs primarily due to a reduction in severance and other payroll-related payments required. During the three and nine months ended September 30, 2016, a net expense reduction of $0.2 million and $0.8 million were accounted for as “general and administrative”, respectively. Additionally, during the nine months ended September 30, 2016, an expense of $0.3 million was accounted for as “research and development” in the condensed consolidated statements of comprehensive loss.

During the three and nine months ended September 30, 2015, the Company incurred $4.6 million and $52.4 million, respectively, in Hyperion acquisition-related costs. During the three and nine months ended September 30, 2015, $2.7 million and $40.5 million were accounted for as “general and administrative expenses”, respectively, $1.9 million and $1.9 million were accounted for as “research and development”, respectively, and zero and $10.0 million were accounted for as “other expenses, net”, respectively, in the condensed consolidated statements of comprehensive loss.

Pursuant to ASC 805, the Company accounted for the Hyperion acquisition as a business combination using the acquisition method of accounting. Identifiable assets and liabilities of Hyperion, including identifiable intangible assets, were recorded based on their estimated fair values as of the date of the closing of the acquisition. The excess of the purchase price over the fair value of the net assets acquired was recorded as goodwill. Significant judgment was required in determining the estimated fair values of developed technology intangible assets and certain other assets and liabilities. Such a valuation required estimates and assumptions including, but not limited to, estimating future cash flows and direct costs in addition to developing the appropriate discount rates and current market profit margins. The Company’s management believes the fair values recognized for the assets acquired and the liabilities assumed are based on reasonable estimates and assumptions.

During the nine months ended September 30, 2016, the Company recorded an adjustment related to deferred tax liabilities which resulted in a decrease to goodwill of $7.2 million. In evaluating whether the Company’s previously issued consolidated financial statements were materially misstated, the Company considered the guidance in FASB ASC Topic 250, Accounting Changes and Error Corrections, ASC Topic 250-10-S99-1, Assessing Materiality, and ASC Topic 250-10-S99-2, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements. The adjustment was the result of a correction of an error in the Hyperion pre-acquisition deferred tax calculation. The Company concluded that this misstatement was not material, individually or in the aggregate, to any of the reporting periods impacted. As such, the correction for this error was made during the three months ended September 30, 2016.

The following table summarizes the final fair values assigned to the assets acquired and the liabilities assumed by the Company (in thousands):

(Liabilities assumed) and assets acquired:	As Reported	Adjustment	As Adjusted
Deferred tax liabilities, net	$(262,732)	$ 7,191	$(255,541)
Accounts payable	(2,439)		(2,439)
Accrued trade discounts and rebates	(9,792)		(9,792)
Accrued expenses	(7,566)		(7,566)
Contingent royalties	(86,800)		(86,800)
Cash and cash equivalents	53,037		53,037
Short-term investments	39,049		39,049
Long-term investments	25,574		25,574
Accounts receivable, net	11,858		11,858

Inventory	13,498		13,498
Prepaid expenses and other current assets	2,533		2,533
Property and equipment	1,044		1,044
Other non-current assets	123		123
Developed technology	1,044,200		1,044,200
Goodwill	253,811	(7,191)	246,620
Fair value of consideration paid	$1,075,398	$ —	$1,075,398

Inventories acquired included raw materials and finished goods. Inventories were recorded at their current fair values. The fair value of finished goods has been determined based on the estimated selling price, net of selling costs and a margin on the selling costs. The fair value of raw materials was estimated to equal the replacement cost. A step up in the value of inventory of $8.7 million was recorded in connection with the acquisition and has subsequently been fully recognized in the condensed consolidated statements of comprehensive loss.

Other tangible assets and liabilities were valued at their respective carrying amounts as management believes that these amounts approximated their acquisition date fair values.

Identifiable intangible assets and liabilities acquired include developed technology and contingent royalties. The fair values of the developed technology and contingent royalties represent valuations performed with the assistance of an independent appraisal firm based on management's estimates, forecasted financial information and reasonable and supportable assumptions.

Developed technology intangible assets reflect the estimated value of Hyperion's rights to its currently marketed medicines, RAVICTI and BUPHENYL. The fair value of developed technology was determined using an income approach. The income approach explicitly recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on current sales projections and estimated direct costs for Hyperion's medicines. Indications of value were developed by discounting these benefits to their acquisition-date worth at a discount rate of 8.5% that reflected the then-current return requirements of the market. The fair value of the RAVICTI and BUPHENYL developed technologies were capitalized as of the Hyperion acquisition date and are subsequently being amortized over 11 and 7 years, respectively, which are the periods in which over 90% of the estimated cash flows are expected to be realized.

The Company has assigned a fair value to a contingent liability for royalties potentially payable under previously existing agreements related to RAVICTI and BUPHENYL. The royalties are payable under the terms of an asset purchase agreement and an amended and restated collaboration agreement with Ucyclyd Pharma, Inc. ("Ucyclyd") and a license agreement with Saul W. Brusilow, M.D. and Brusilow Enterprises Inc. (together "Brusilow"). See Note 12 for details of the percentages payable under such agreements. The initial fair value of this liability was $86.8 million and was determined using a discounted cash flow analysis incorporating the estimated future cash flows of royalty payments resulting from future sales. The discount rate used was the same as for the fair value of the developed technology.

Deferred tax assets and liabilities arise from acquisition accounting adjustments where book values of certain assets and liabilities differ from their tax bases. 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. Hyperion's developed technology as of the acquisition date was located primarily in the United States where a U.S. tax rate of 39% is being utilized and a significant deferred tax liability is recorded. Upon consummation of the Hyperion acquisition, Hyperion became a member of the Company's U.S. tax consolidation group. As such, its tax assets and liabilities were considered in determining the appropriate amount (if any) of valuation allowances that should be recognized in assessing the realizability of the group's deferred tax assets. The Hyperion acquisition adjustments resulted in the recognition of significant net deferred tax liabilities. Per ASC Topic 740, Accounting for Uncertainty in Income Taxes, future reversals of existing taxable temporary differences provide objectively verifiable evidence that should be considered as a source of taxable income to realize a tax benefit for deductible temporary differences and carryforwards. Generally, the existence of sufficient taxable temporary differences will enable the use of the tax benefit of existing deferred tax assets. As of the first quarter of 2015, the Company had significant U.S. federal and state valuation allowances. These valuation allowances were released in the second quarter of 2015 to reflect the recognition of Hyperion's deferred tax liabilities that will provide taxable temporary differences that will be realized within the carryforward period of the Company's U.S. tax consolidation group's available net operating losses and other deferred tax assets. Accordingly, the Company recorded an income tax benefit of $105.1 million in the second quarter of 2015 relating to the release of existing U.S. federal and state valuation allowances.

Short-term and long-term investments included in the table above represent available-for-sale securities that were reported in short-term investments or long-term investments based on maturity dates and whether such assets are reasonably expected to be realized in cash or sold or consumed during the normal cycle of business. Available-for-sale investments were recorded at fair value and were liquidated shortly after the acquisition.

Goodwill represents the excess of the acquisition consideration over the estimated fair value of net assets acquired and was recorded in the condensed consolidated balance sheet as of the acquisition date. The Company does not expect any portion of this goodwill to be deductible for tax purposes.

Pro Forma Information

The table below represents the condensed consolidated financial information for the Company for the nine months ended September 30, 2015 on a pro forma basis, assuming that the Crealta and Hyperion acquisitions occurred as of January 1, 2015. The historical financial information has been adjusted to give effect to pro forma items that are directly attributable to the Crealta and Hyperion acquisitions, and are expected to have a continuing impact on the consolidated results. These items include, among others, adjustments to record the amortization of definite-lived intangible assets, interest expense, debt discount and deferred financing costs associated with the debt in connection with the acquisitions.

The Company does not believe that the pre-acquisition operating results for Crealta during January 2016 are material to the combined entity and as such the Company did not prepare an unaudited pro forma combined statement of operations for the nine months ended September 30, 2016.

Additionally, the following table sets forth unaudited financial information and has been compiled from historical financial statements and other information, but is not necessarily indicative of the results that actually would have been achieved had the transactions occurred on the dates indicated or that may be achieved in the future (in thousands):

	For the Nine Months Ended September 30, 2015		
		Pro forma	
	As reported	adjustments	Pro forma
Net sales	$512,506	$ 84,942	$597,448
Net income (loss)	15,538	(46,420)	(30,882)

The Company's unaudited condensed consolidated statements of comprehensive loss for the nine months ended September 30, 2016 include KRYSTEXXA and MIGERGOT net sales as a result of the acquisition of Crealta of $61.6 million and $3.2 million, respectively, and RAVICTI and BUPHENYL net sales as a result of the acquisition of Hyperion of $118.6 million and $12.1 million, respectively. The Company's unaudited condensed consolidated statements of comprehensive loss for the nine months ended September 30, 2015 include RAVICTI and BUPHENYL net sales as a result of the acquisition of Hyperion of $52.4 million and $7.8 million, respectively.

Crealta and Hyperion have been fully integrated into the Company's business and as a result of these integration efforts, the Company cannot distinguish between these operations and those of the Company's legacy business.

NOTE 4 – 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 September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Raw materials	$3,660	$6,232
Work-in-process	114,049	631

Finished goods	44,446	11,513
Inventories, net	$ 162,155	$ 18,376

Work-in-process at September 30, 2016 included $101.7 million of stepped-up KRYSTEXXA and MIGERGOT inventory. Finished goods at September 30, 2016 included $32.3 million of stepped-up KRYSTEXXA and MIGERGOT inventory. The Company amortized $11.3 million and $27.9 million of the KRYSTEXXA and MIGERGOT inventory step-up during the three and nine months ended September 30, 2016, respectively.

NOTE 5 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Prepaid income taxes	$ 13,413	$ 4
Medicine samples inventory	8,723	4,697
Prepaid co-pay expenses	2,022	1,881
Rabbi trust assets	2,740	773
Other prepaid expenses	11,180	8,503
Prepaid expenses and other current assets	$ 38,078	$ 15,858

NOTE 6 – PROPERTY AND EQUIPMENT

Property and equipment as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Software	$ 10,005	$ 1,360
Leasehold improvements	8,781	1,966
Computer equipment	2,975	2,514
Machinery and equipment	2,843	2,946
Other	1,763	276
	26,367	9,062
Less accumulated depreciation	(6,839)	(3,791)
Construction in process	—	3,492
Software implementation in process	1,914	5,257
Property and equipment, net	$ 21,442	$ 14,020

The Company capitalizes development costs associated with internal use software, including external direct costs of materials and services and payroll costs for employees devoting time to a software project. Costs incurred during the preliminary project stage, as well as costs for maintenance and training, are expensed as incurred.

Software implementation in process as of September 30, 2016 and December 31, 2015 is related to new enterprise resource planning software being implemented by the Company. The software is being implemented on a phased basis starting January 2016 and depreciation is not recorded on capitalized costs relating to a phase which has not yet entered service. Once a particular phase of the project enters service, associated capitalized costs are moved from “software implementation in process” to “software” in the table above, and depreciation commences.

Depreciation expense was $1.2 million and $1.6 million for the three months ended September 30, 2016 and 2015, respectively, and was $3.3 million and $2.8 million for the nine months ended September 30, 2016 and 2015, respectively.

NOTE 7 – GOODWILL AND INTANGIBLE ASSETS

Goodwill

The gross carrying amount of goodwill as of September 30, 2016 was as follows (in thousands):

Balance at December 31, 2015	$253,811

Acquired during the period	2,116
Adjustment relating to the prior year	(7,191)
Balance at September 30, 2016	$248,736

In May 2015, the Company recognized goodwill with a value of $253.8 million in connection with the Hyperion acquisition, which represented the excess of the purchase price over the fair value of the net assets acquired. During the nine months ended September 30, 2016, the Company recorded an adjustment related to deferred tax liabilities which resulted in a decrease to goodwill of $7.2 million. The adjustment was the result of a correction of an error in the Hyperion pre-acquisition deferred tax calculation. The Company concluded that this misstatement was not material, individually or in the aggregate, to any of the reporting periods impacted. As such, the correction for this error was made during the three months ended September 30, 2016.

In January 2016, the Company recognized goodwill with a preliminary value of $1.8 million in connection with the Crealta acquisition, which represented the excess of the purchase price over the fair value of the net assets acquired. During the nine months ended September 30, 2016, the Company recorded measurement period adjustments related to developed technology and inventory, which resulted in a net increase in goodwill of $0.3 million.

See Note 3 for further details of goodwill acquired in business acquisitions.

As of September 30, 2016, there were no accumulated goodwill impairment losses.

Intangible Assets

The Company's intangible assets consist of developed technology related to ACTIMMUNE, BUPHENYL, KRYSTEXXA, MIGERGOT, PENNSAID 2%, RAVICTI, RAYOS and VIMOVO in the United States, and AMMONAPS and LODOTRA in Europe, as well as in-process research and development ("IPR&D") and customer relationships for ACTIMMUNE.

In May 2015, in connection with the acquisition of Hyperion, the Company capitalized $1,021.6 million of developed technology related to RAVICTI and $22.6 million of developed technology related to BUPHENYL.

In January 2016, in connection with the acquisition of Crealta, the Company capitalized $392.7 million of developed technology related to KRYSTEXXA and $24.6 million of developed technology related to MIGERGOT. During the nine months ended September 30, 2016, the Company recorded a measurement period adjustment which increased the cost basis of MIGERGOT developed technology by $1.4 million, to $26.0 million.

See Note 3 for further details of intangible assets acquired in business acquisitions.

IPR&D is related to one research and development project for the application of ACTIMMUNE in the treatment of FA. The fair value of the IPR&D was recorded as an indefinite-lived intangible asset and is tested for impairment annually until completion or abandonment of research and development efforts associated with the project. IPR&D is not amortized until successful completion of the project. In June 2015, the Company initiated the Phase 3 Safety, Tolerability and Efficacy of ACTIMMUNE Dose Escalation in Friedreich's Ataxia Study ("STEADFAST study") of ACTIMMUNE for the treatment of FA. The Company expects to have top-line results from the STEADFAST study in late December 2016.

After receiving the results from the STEADFAST study, the Company will assess the impact of the results on the accounting for the IPR&D intangible asset. Possible accounting treatments include the commencement of amortization of the intangible asset following approval by the FDA, or the recording of an impairment charge if the study is unsuccessful.

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. The Company does not believe there have been any circumstances or events that would indicate that the carrying value of any of its intangible assets was impaired at September 30, 2016 or December 31, 2015.

As of September 30, 2016 and December 31, 2015, amortizable intangible assets consisted of the following (in thousands):

	September 30, 2016			December 31, 2015		
	Cost Basis	Accumulated Amortization	Net Book Value	Cost Basis	Accumulated Amortization	Net Book Value
Developed technology	$2,211,195	$ (334,037)	$1,877,158	$1,792,495	$ (183,446)	$1,609,049
Customer relationships	8,100	(1,647)	6,453	8,100	(1,039)	7,061
Total amortizable intangible assets	$2,219,295	$ (335,684)	$1,883,611	$1,800,595	$ (184,485)	$1,616,110

Amortization expense for the three months ended September 30, 2016 and 2015 was $50.8 million and $41.7 million, respectively, and was $151.2 million and $91.2 million for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, estimated future amortization expense was as follows (in thousands):

2016 (October to December)	$50,619
2017	203,086
2018	203,086
2019	190,094
2020	189,875
Thereafter	1,046,851
Total	$1,883,611

NOTE 8 – ACCRUED TRADE DISCOUNTS AND REBATES

Accrued trade discounts and rebates as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Accrued wholesaler fees and commercial rebates	$27,965	$21,112
Accrued co-pay and other patient assistance	173,229	114,201
Accrued government rebates and chargebacks	67,008	48,456
Accrued trade discounts and rebates	268,202	183,769
Invoiced wholesaler fees and commercial rebates, co-pay and other patient assistance, and government rebates and chargebacks in accounts payable	42,466	—
Total customer-related accruals and allowances	$310,668	$183,769

The following table summarizes changes in the Company's customer-related accruals and allowances from December 31, 2015 to September 30, 2016 (in thousands):

	Wholesaler Fees and Commercial Rebates	Co-Pay and Other Patient Assistance	Government Rebates and Chargebacks	Total
Balance at December 31, 2015	$ 21,112	$114,201	$48,456	$183,769
Current provisions relating to sales in the nine months ended September 30, 2016	82,232	1,275,181	205,437	1,562,850
Adjustments relating to prior year sales	2,812	—	(7,043)	(4,231)
Payments relating to sales in the nine months ended September 30, 2016	(57,921)	(1,065,202)	(133,763)	(1,256,886)
Payments relating to sales in prior years	(20,644)	(114,201)	(41,413)	(176,258)
Crealta acquisition on January 13, 2016	492	—	932	1,424
Balance at September 30, 2016	$ 28,083	$209,979	$72,606	$310,668

NOTE 9 – ACCRUED EXPENSES

Accrued expenses as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Litigation settlement	$65,000	$—
Payroll-related expenses	35,004	47,205
Consulting and professional services	25,664	17,160
Accrued interest	16,223	10,637
Accrued other	15,643	25,044
Accrued expenses	$157,534	$100,046

Accrued expenses as of September 30, 2016 include $65.0 million in relation to a litigation settlement with Express Scripts, Inc. (“Express Scripts”). See Note 12 for further details of this settlement.

NOTE 10 – ACCRUED ROYALTIES

During the nine months ended September 30, 2016, changes to the liability for royalties for medicines acquired through business combinations consisted of the following (in thousands):

Balance as of December 31, 2015	$175,219
Assumed KRYSTEXXA and MIGERGOT accrued royalties	1,401
Assumed KRYSTEXXA and MIGERGOT contingent royalty liabilities	51,300
Royalty payments	(27,888)
Accretion expense	28,762
Balance as of September 30, 2016	228,794
Less: Current portion	59,176
Accrued royalties, net of current	$169,618

The Company did not record any remeasurements of contingent royalty liabilities during the nine months ended September 30, 2016, as there were no triggering events during the period.

The top-line results from the STEADFAST study are expected in late December 2016. The Company may then seek approval of ACTIMMUNE for the treatment of FA from the FDA, which may result in a remeasurement of contingent royalty liabilities.

NOTE 11 – 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 September 30, 2016, 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 recorded at fair value on a recurring basis are composed of investments held in a rabbi trust related to deferred compensation arrangements. Quoted prices for these investments, primarily in mutual funds, are available in active markets. Thus, the Company's investments related to deferred compensation arrangements 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 in 2016 or 2015.

Assets and liabilities measured at fair value on a recurring basis

The following table sets forth the Company's financial assets and liabilities at fair value on a recurring basis as of September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016			
	Level 1	Level 2	Level 3	Total
Assets:				
Bank time deposits	$—	$2,504	$ —	$2,504
Money market funds	430,000	—	—	430,000
Other current assets	2,740	—	—	2,740
Total assets at fair value	$432,740	$2,504	$ —	$435,244

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Assets:				
Bank time deposits	$—	$1,000	$ —	$1,000
Money market funds	280,053	—	—	280,053
Other current assets	773	—	—	773
Total assets at fair value	$280,826	$1,000	$ —	$281,826

NOTE 12 – COMMITMENTS AND CONTINGENCIES

Lease Obligations

The Company has the following lease agreements in place for real properties:

Location	Approximate Square Footage	Lease Expiry Date
Dublin, Ireland	18,900	November 3, 2029
Lake Forest, Illinois (1)	160,000	March 31, 2024
Deerfield, Illinois (2)	53,500	June 30, 2018
Brisbane, California (3)	20,100	November 30, 2019
Mannheim, Germany	14,300	December 31, 2018
Chicago, Illinois	6,500	December 31, 2018
Reinach, Switzerland	3,500	May 31, 2020

(1) In connection with the Lake Forest, Illinois lease, the Company has provided a $2.1 million letter of credit to the landlord, through a commercial bank. The Company has two separate lease agreements in place for this property,

one of which, consisting of approximately 15,000 square feet, was assumed by the Company as a result of its acquisition of Crealta in January 2016 and will expire on October 31, 2017.

(2) The Company vacated the premises in Deerfield, Illinois in January 2016.

(3) The Company vacated the premises in Brisbane, California in December 2015 and entered into a sublease agreement for the property with Raptor in January 2016. See Note 3 for details of the Company's acquisition of Raptor in October 2016. Since the closing of the Raptor acquisition, this sublease has been between subsidiaries of the Company and the premises are no longer considered vacated.

Purchase Commitments

In August 2007, the Company entered into a manufacturing and supply agreement with Jagotec AG ("Jagotec"). Under the agreement, Jagotec or its affiliates are required to manufacture and supply RAYOS/LODOTRA exclusively to the Company in bulk. The Company committed to a minimum purchase of RAYOS/LODOTRA tablets from Jagotec for an initial five years from the date of first launch of RAYOS/LODOTRA in a major country, as defined in the agreement, which was April 2009. Thereafter, the agreement automatically renews on a yearly basis until either party provides two years advance written notice of termination. In April 2016 the agreement automatically renewed, therefore the earliest the agreement can expire according to this advance notice procedure is April 15, 2019, and the minimum purchase commitment is in force until April 2019. At September 30, 2016, the minimum purchase commitment based on tablet pricing in effect under the agreement was $2.1 million through April 2019.

In May 2011, the Company entered into a manufacturing and supply agreement with Sanofi-Aventis U.S. LLC ("Sanofi-Aventis U.S."), and amended the agreement effective as of September 25, 2013. Pursuant to the agreement, as amended, 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. At September 30, 2016, the Company had a binding purchase commitment to Sanofi-Aventis U.S. for DUEXIS of $4.6 million, which is to be delivered through December 2016.

In July 2013, Vidara and Boehringer Ingelheim RCV GmbH & Co. KG ("Boehringer Ingelheim") entered into an exclusive supply agreement, which the Company assumed as a result of the Vidara Merger and amended effective as of June 1, 2015. Under the agreement, Boehringer Ingelheim is required to manufacture and supply interferon gamma-1b (ACTIMMUNE) to the Company. The Company is required to purchase minimum quantities of finished medicine per annum through July 2020. As of September 30, 2016, the minimum binding purchase commitment to Boehringer Ingelheim was $13.7 million (converted using a Euro-to-Dollar exchange rate of 1.1240) through July 2020.

In October 2016, the Company committed to purchase additional units of ACTIMMUNE from Boehringer Ingelheim in 2017 at a cost of $7.3 million (converted using a Euro-to-Dollar exchange rate of 1.1240). These additional units of ACTIMMUNE are intended to cover anticipated demand if the results of the STEADFAST study of ACTIMMUNE for the treatment of FA are successful and the Company subsequently receives U.S. marketing approval for FA. Top-line results from the study are expected in late December 2016, and if the trial is not successful, the Company may have excess ACTIMMUNE inventory and/or purchase commitments.

In November 2013, the Company entered into a long-term master manufacturing services and product agreement with Patheon Pharmaceuticals Inc. ("Patheon") pursuant to which Patheon is obligated to manufacture VIMOVO for the Company through December 31, 2019. The Company agreed to purchase a specified percentage of VIMOVO requirements for the United States from Patheon. The Company must pay an agreed price for final, packaged VIMOVO supplied by Patheon as set forth in the Patheon manufacturing agreement, subject to adjustments, including certain unilateral adjustments by Patheon, such as annual adjustments for inflation and adjustments to account for certain increases in the cost of components of VIMOVO other than active materials. The Company issues 12-month forecasts of the volume of VIMOVO that the Company expects to order. The first six months of the forecast are considered binding firm orders. At September 30, 2016, the Company had a binding purchase commitment with Patheon for VIMOVO of $0.5 million through December 2016.

In October 2014, in connection with the acquisition of the U.S. rights to PENNSAID 2% from Nuvo, the Company and Nuvo entered into an exclusive supply agreement, which was amended in February 2016. Under the supply agreement, 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 90 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 September 30, 2016, the Company had a binding purchase commitment with Nuvo for PENNSAID 2% of $3.9 million through December 2016.

Purchase orders relating to the manufacture of RAVICTI and BUPHENYL of $3.6 million were outstanding at September 30, 2016.

In March 2007, Savient Pharmaceuticals, Inc. (as predecessor in interest to Crealta), entered into a commercial supply agreement with Bio-Technology General (Israel) Ltd ("BTG Israel") for the production of the bulk KRYSTEXXA medicine ("bulk product"). The Company assumed this agreement as part of the Crealta acquisition and amended the agreement in September 2016 (the "September 2016 Amendment"). Under this agreement, the Company has agreed to purchase certain minimum annual order quantities and is obligated to purchase at least 80 percent of its annual world-wide bulk product requirements 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 and the Company may be required to pay the OCS additional amounts as a repayment for the OCS grant funding. In December 2015, Crealta received a notice of termination from BTG Israel and, as of the Crealta acquisition date, it had been considered probable that the manufacture of the KRYSTEXXA bulk product would be moved outside of Israel and the Company would have been required to pay additional amounts estimated at approximately $6.9 million. This estimated obligation was recorded as an assumed contingent liability as of the Crealta acquisition date (see Note 3 for further details) and was included in "Other long-term liabilities" in the condensed consolidated balance sheet. Following the execution of the September 2016 Amendment, the Company determined it would not move the manufacture of the KRYSTEXXA bulk product outside of Israel, and released the $6.9 million assumed contingent liability to "Other income (expense)" in the condensed consolidated statement of comprehensive loss during the three months ended September 30, 2016. The Company issues 18-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 September 30, 2016, the Company had a binding purchase commitment with BTG Israel for KRYSTEXXA of $0.2 million through December 2016, and $5.0 million per annum thereafter.

Royalty Agreements

RAYOS/LODOTRA

In connection with an August 2004 development and license agreement with SkyePharma AG, who subsequently entered into a business combination with Vectura Group plc ("Vectura"), and Jagotec, a wholly owned subsidiary of Vectura, regarding certain proprietary technology and know-how owned by Vectura, Jagotec is entitled to receive a single digit percentage royalty on net sales of RAYOS/LODOTRA and on any sub-licensing income, which includes any payments not calculated based on the net sales of RAYOS/LODOTRA, such as license fees, lump sums and milestone payments.

VIMOVO

The Company entered into a license agreement with Pozen Inc., who subsequently entered into a business combination with Tribute Pharmaceuticals Canada Inc. to become known as Aralez Pharmaceuticals Inc. ("Aralez"). Under this agreement, the Company is required to pay Aralez a flat 10% royalty on net sales of VIMOVO and other medicines sold by the Company, its affiliates or sublicensees during the royalty term that contain gastroprotective agents in a single fixed combination oral solid dosage form with nonsteroidal anti-inflammatory drugs, subject to minimum annual royalty obligations of $7.5 million. These minimum royalty obligations will continue for each year during which one of Aralez's patents covers such medicines in the United States and there are no competing medicines in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing medicines. The Company's obligation to pay royalties to Aralez will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such medicines in the United States, and (b) ten years

after the first commercial sale of such medicines in the United States.

ACTIMMUNE

Under a license agreement, as amended, with Genentech Inc. ("Genentech"), who was the original developer of ACTIMMUNE, the Company is or was obligated to pay royalties to Genentech on its net sales of ACTIMMUNE as follows:

- Through November 25, 2014, a royalty of 45% of the first $3.7 million in net sales achieved in a calendar year, and 10% on all additional net sales in that year;
- For the period from November 26, 2014 through May 5, 2018, a royalty in the 20% to 30% range for the first tier in net sales and in the 1% to 9% range for the second tier; and
- From May 6, 2018 and for so long as the Company continues to commercially sell ACTIMMUNE, an annual royalty in the low single digits as a percentage of annual net sales.

Under the terms of an assignment and option agreement with Connetics, the Company is obligated to pay royalties to Connetics on the Company's net sales of ACTIMMUNE as follows:

- 0.25% of net sales of ACTIMMUNE, rising to 0.5% once cumulative net sales of ACTIMMUNE in the United States surpass $1.0 billion; and in the event the Company develops and receives regulatory approval for ACTIMMUNE in the indication of scleroderma, the Company will be obligated to pay a royalty of 4% on all net sales of ACTIMMUNE recorded for use in that indication.

RAVICTI

Under the terms of an asset purchase agreement with Ucyclyd, the Company is obligated to pay to Ucyclyd tiered mid to high single-digit royalties on its global net sales of RAVICTI. Under the terms of a license agreement with Brusilow, the Company is obligated to pay low single-digit royalties to Brusilow on net sales of RAVICTI that are covered by a valid claim of a licensed patent.

BUPHENYL

Under the terms of an amended and restated collaboration agreement with Ucyclyd, the Company is obligated to pay to Ucyclyd tiered mid to high single-digit royalties on its net sales in the United States of BUPHENYL to urea cycle disorder patients outside of the U.S. Food and Drug Administration ("FDA") approved labeled age range for RAVICTI.

KRYSTEXXA

Under the terms of a license agreement with Duke and MVP, the Company is obligated to pay Duke a mid-single digit royalty on its global net sales of KRYSTEXXA and a low-double digit royalty on any global sublicense revenue. The Company is also obligated to pay MVP a mid-single digit royalty on its net sales of KRYSTEXXA outside of the United States and a low-double digit royalty on any sublicense revenue outside of the United States.

The royalty obligations described above are included in accrued royalties on the Company's condensed consolidated balance sheets.

For all of the royalty agreements entered into by the Company, a total expense of $11.2 million and $32.6 million was recorded in cost of goods sold for the three and nine months ended September 30, 2016, respectively. The total expense recorded in cost of goods sold for the three and nine months ended September 30, 2015 was $6.6 million and $28.0 million, respectively.

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, Express Scripts filed suit against the Company in Delaware Superior Court, Newcastle County, asserting claims for breach of contract, breach of the implied covenant of good faith and fair dealing, unjust enrichment, and declaratory relief arising from the parties' 2012 Preferred Savings Grid Rebate Program Agreement. The Company filed a counter-claim against Express Scripts for breach of contract, breach of the implied covenant of good faith and fair dealing, and declaratory relief arising from Express Scripts' breach of the rebate agreement. In September 2016, the Company entered into a settlement agreement and mutual release with Express Scripts pursuant

to which the Company and Express Scripts were released from any and all claims relating to the litigation without admitting any fault or wrongdoing and the Company agreed to pay Express Scripts $65.0 million. The settlement amount will be paid to Express Scripts in installments, with 50 percent of the installment due in the fourth quarter of 2016, 25 percent in the first quarter of 2017 and 25 percent in the second quarter of 2017. The full amount of this settlement has been accounted for as a reduction of “net sales” in the condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2016.

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 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 13 below), the Company has received notice from the Underwriter Defendants (as defined below) of their intention to seek indemnification and has received, but not yet paid, several invoices from the Underwriter Defendants. 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 13 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 future potential claims. Certain of the Company's officers and directors had also entered into separate indemnification agreements with HPI prior to the Vidara Merger.

NOTE 13 – LEGAL PROCEEDINGS

On July 15, 2013, the Company received a Paragraph IV Patent Certification from Watson Laboratories, Inc.—Florida, known as Actavis Laboratories FL, Inc. ("Actavis FL"), advising that Actavis FL had filed an Abbreviated New Drug Application ("ANDA") with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. On August 26, 2013, the Company, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Actavis FL, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc. seeking an injunction to prevent the approval of the ANDA.

On October 1, 2015, the Company's subsidiary Horizon Pharma Switzerland GmbH, as well as Jagotec, entered into a license and settlement agreement (the "Actavis settlement agreement") with Actavis FL relating to the Company's and Jagotec's patent infringement litigation against Actavis FL. In accordance with legal requirements, the Company, Jagotec and Actavis FL agreed to submit the Actavis settlement agreement to the U.S. Federal Trade Commission ("FTC") and the U.S. Department of Justice ("DOJ") for review. The parties submitted the Actavis settlement agreement to the FTC and DOJ for review and no issues were raised by either. The parties agreed to file stipulations of dismissal with the court regarding the litigation and the court entered the stipulation and closed the case on December 4, 2015. The Actavis settlement agreement provides for a full settlement and release by each party of all claims that relate to the litigation or under the patents with respect to Actavis FL's generic version of RAYOS tablets.

Under the Actavis settlement agreement, the Company and Jagotec granted Actavis FL a non-exclusive license to manufacture and commercialize Actavis FL's generic version of RAYOS tablets in the United States after the generic

entry date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Actavis FL's generic version of RAYOS tablets during certain limited periods prior to the generic entry date. The Company and Jagotec also agreed that during the 180 days after the generic entry date, the license granted to Actavis FL would be exclusive with respect to any third-party generic version of RAYOS tablets.

Under the Actavis settlement agreement, the generic entry date is December 23, 2022; however, Actavis FL may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party RAYOS patent litigation, the entry of other generic versions of RAYOS tablets or certain substantial reductions in RAYOS prescriptions over specified periods of time.

The Company and Jagotec also agreed not to sue or assert any claim against Actavis FL for infringement of any patent or patent application owned or controlled by the Company or Jagotec during the term of the Actavis settlement agreement based on Actavis FL's generic version of RAYOS tablets in the United States. In turn, Actavis FL agreed not to challenge the validity or enforceability of the licensed patents.

If the Company or Jagotec enter into any similar agreements with other parties with respect to generic versions of RAYOS tablets, the Company and Jagotec agreed to amend the Actavis settlement agreement to provide Actavis FL with terms that are no less favorable than those provided to such other parties with respect to the license terms, generic entry date, permitted pre-market activities and notice provisions.

On November 13, 2014, the Company received a Paragraph IV Patent Certification from Watson Laboratories, Inc. ("Watson Laboratories") advising that Watson Laboratories had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On December 23, 2014, the Company filed suit in the United States District Court for the District of New Jersey against Watson Laboratories, Actavis, Inc., and Actavis plc (collectively "Actavis") seeking an injunction to prevent the approval of the ANDA. Since then, Watson Laboratories, Inc. changed its name to Actavis Laboratories UT, Inc., and remains the current holder of the ANDA. The lawsuit alleged that Actavis has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 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 FDA's Orange Book ("Orange Book"). The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Actavis' ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid.

On June 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patent No. 9,066,913. On August 11, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patent No. 9,101,591. On September 17, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patent No. 9,132,110. All three patents, U.S. Patent Nos. 9,066,913, 9,101,591, and 9,132,110 are listed in the Orange Book and have claims that cover PENNSAID 2%. These three cases have since been consolidated with the case filed against Actavis on December 23, 2014.

On October 27, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patent Nos. 9,168,304 and 9,168,305. On February 5, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patent No. 9,220,784. All three patents, U.S. Patent Nos. 9,168,304, 9,168,305, and 9,220,784 are listed in the Orange Book and have claims that cover PENNSAID 2%.

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 U.S. Patent Nos. 9,339,551, 9,339,552, 9,370,501, and 9,375,412. All four patents, U.S. Patent Nos. 9,339,551, 9,339,552, 9,370,501, and 9,375,412, are listed in the Orange Book and have claims that cover PENNSAID 2%. All of the litigation against Actavis remains pending. No trial date for any of the Actavis actions has been set by the court.

The Company received from Actavis a Paragraph IV Patent Certification Notice Letter dated September 27, 2016, against Orange Book listed U.S. Patent Nos. 9,415,029, advising that Actavis had filed an ANDA with the FDA for a generic version of PENNSAID 2%.

On December 2, 2014, the Company received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,741,956 from Paddock Laboratories, LLC ("Paddock") advising that Paddock had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On January 9, 2015, the Company received from Paddock another Paragraph IV Patent Certification against newly Orange Book listed U.S. Patent No. 8,871,809. On January 13, 2015 and January 14, 2015, the Company filed suits in the United States District Court for the District of New Jersey and the United States District Court for the District of Delaware, respectively, against Paddock seeking an injunction to prevent the approval of the ANDA. The lawsuits alleged that Paddock has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 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 May 6, 2015, the Company entered into a settlement and license agreement (the "Perrigo settlement agreement") with Perrigo Company plc and its subsidiary Paddock (collectively, "Perrigo"), relating to the Company's patent

infringement litigation against Perrigo. The Perrigo settlement agreement provides for a full settlement and release by both the Company and Perrigo of all claims that were or could have been asserted in the litigation and that arise out of the issues that were the subject of the litigation or Perrigo's generic version of PENNSAID 2%. The Perrigo settlement agreement also contemplated the filing of a joint stipulation of dismissal by the parties. This stipulation of dismissal was entered by the district court on May 13, 2015.

Under the Perrigo settlement agreement, the Company granted Perrigo a non-exclusive license to manufacture and commercialize Perrigo's generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Perrigo's generic version of PENNSAID 2% during certain limited periods prior to the license effective date.

Under the Perrigo settlement agreement, the license effective date is January 10, 2029; however, Perrigo may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in the Company's PENNSAID 2% shipments over specified periods of time.

Under the Perrigo settlement agreement, the Company also agreed not to sue or assert any claim against Perrigo for infringement of any patent or patent application owned or controlled by the Company during the term of the license granted in the Perrigo settlement agreement based on the manufacture, use, sale, offer for sale, or importation of Perrigo's generic version of PENNSAID 2% in the United States.

In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, the Company may be required to supply Perrigo PENNSAID 2% as its authorized distributor of generic PENNSAID 2%, with the Company receiving specified percentages of any net sales by Perrigo. The Company also agreed that if it enters into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, the Company will amend the Perrigo settlement agreement to provide Perrigo with terms that are no less favorable than those provided to such other parties.

On February 2, 2015, the Company received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 from Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (collectively, "Taro") advising that Taro had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On March 13, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Taro seeking an injunction to prevent the approval of the ANDA.

On September 9, 2015, certain subsidiaries of the Company (the "Horizon Subsidiaries") entered into a settlement and license agreement with Taro (the "Taro settlement agreement") relating to the Horizon Subsidiaries' patent infringement litigation against Taro. In accordance with legal requirements, the Horizon Subsidiaries and Taro submitted the Taro settlement agreement to the FTC and DOJ for review, and no issues have been raised by the FTC and DOJ. The Horizon Subsidiaries and Taro have also filed stipulations of dismissal with the courts regarding the litigation, with these dismissals being entered by the district court on November 3, 2015. The Taro settlement agreement provides for a full settlement and release by both us and Taro of all claims that were or could have been asserted in the Litigation and that arise out of the issues that were subject of the litigation or Taro's generic version of PENNSAID 2%.

Under the Taro settlement agreement, the Horizon Subsidiaries granted Taro a non-exclusive license to manufacture and commercialize Taro's generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Taro's generic version of PENNSAID 2% during certain limited periods prior to the license effective date.

Under the Taro settlement agreement, the license effective date is January 10, 2029; however, Taro may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in the Company's PENNSAID 2% shipments over specified periods of time.

Under the Taro settlement agreement, the Horizon Subsidiaries also agreed not to sue or assert any claim against Taro for infringement of any patent or patent application owned or controlled by the Horizon Subsidiaries during the term of the license granted in the Taro settlement agreement based on the manufacture, use, sale, offer for sale, or importation of Taro's generic version of PENNSAID 2% in the United States.

The Horizon Subsidiaries also agreed that if they enter into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, the Horizon Subsidiaries will amend the Taro settlement agreement to provide Taro with terms that are no less favorable than those provided to the other parties.

On March 18, 2015, the Company received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 from Lupin Limited

advising that Lupin Limited had filed an ANDA with the FDA for 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 Limited and Lupin Pharmaceuticals Inc. (collectively, "Lupin"), seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Lupin has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 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. 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.

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 U.S. Patent No. 9,066,913. 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 U.S. Patent No. 9,101,591 to the litigation with respect to U.S. Patent No. 9,066,913. On September 17, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patent No. 9,132,110. All three patents, U.S. Patent Nos. 9,066,913, 9,101,591, and 9,132,110 are listed in the Orange Book and have claims that cover PENNSAID 2%.

On October 27, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patent Nos. 9,168,304 and 9,168,305. On February 5, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patent No. 9,220,784. On August 18, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patent Nos. 9,339,551, 9,339,552, 9,370,501, and 9,375,412. All seven patents, U.S. Patent Nos. 9,168,304, 9,168,305, 9,220,784, 9,339,551, 9,339,552, 9,370,501, and 9,375,412 are listed in the Orange Book and have claims that cover PENNSAID 2%. All of the infringement actions brought against Lupin remain pending. The court has not yet set a trial date for the Lupin actions.

The Company received from Teligent, Inc., formerly known as IGI Laboratories, Inc. ("Teligent"), a Paragraph IV Patent Certification dated March 24, 2015 against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 advising that Teligent had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On May 21, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Teligent has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 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. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Teligent's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid.

On June 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent No. 9,066,913. On August 11, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent No. 9,101,591. On September 17, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent No. 9,132,110. All three patents, U.S. Patent Nos. 9,066,913, 9,101,591, and 9,132,110 are listed in the Orange Book and have claims that cover PENNSAID 2%.

On October 27, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent Nos. 9,168,304 and 9,168,305. On February 5, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent No. 9,220,784. All three patents, U.S. Patent Nos. 9,168,304, 9,168,305, and 9,220,784 are listed in the Orange Book and have claims that cover PENNSAID 2%.

The Company entered into a settlement and license agreement with Teligent (the "Teligent settlement agreement"), effective May 9, 2016, relating to the patent infringement litigation against Teligent. In accordance with legal requirements, the Company and Teligent submitted the Teligent settlement agreement to the FTC and DOJ for review, and no issues have been raised by the FTC and DOJ. The Company and Teligent have also filed stipulations of dismissal with the district court regarding the litigation, with these dismissals having been entered by the district court on May 2, 2016. The Teligent settlement agreement provides for a full settlement and release by both the Company and Teligent of all claims that were or could have been asserted in the litigation and that arise out of the issues that were subject of the litigation or Teligent's generic version of PENNSAID 2%.

Under the Teligent settlement agreement, the Company granted Teligent a non-exclusive license to manufacture and commercialize Teligent's generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Teligent's generic version of PENNSAID 2% during certain limited periods prior to the license effective date.

Under the Teligent settlement agreement, the license effective date is January 10, 2029; however, Teligent may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other

third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in the Company's PENNSAID 2% shipments over specified periods of time.

Under the Teligent settlement agreement, the Company also agreed not to sue or assert any claim against Teligent for infringement of any patent or patent application owned or controlled by the Company during the term of the license granted in the Teligent settlement agreement based on the manufacture, use, sale, offer for sale, or importation of Teligent's generic version of PENNSAID 2% in the United States.

In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, the Company may be required to supply Teligent PENNSAID 2% as an authorized distributor of generic PENNSAID 2%, with the Company receiving specified percentages of any net sales by Teligent. The Company also agreed that if it enters into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, the Company will amend the Teligent settlement agreement to provide Teligent with terms that are no less favorable than those provided to the other parties.

The Company received from Amneal Pharmaceuticals LLC ("Amneal") a Paragraph IV Patent Certification dated April 2, 2015 against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 advising that Amneal had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On May 15, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Amneal has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 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. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Amneal's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid.

On June 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent No. 9,066,913. On August 11, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent No. 9,101,591. On September 17, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent No. 9,132,110. All three patents, U.S. Patent Nos. 9,066,913, 9,101,591, and 9,132,110 are listed in the Orange Book and have claims that cover PENNSAID 2%.

On October 27, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent Nos. 9,168,304 and 9,168,305. On February 5, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent No. 9,220,784. All three patents, U.S. Patent Nos. 9,168,304, 9,168,305, and 9,220,784 are listed in the Orange Book and have claims that cover PENNSAID 2%.

On April 18, 2016, the Company entered into a settlement and license agreement (the "Amneal settlement agreement") with Amneal relating to the Company's patent infringement litigation against Amneal. In accordance with legal requirements, the Company and Amneal submitted the Amneal settlement agreement to the FTC and DOJ for review, and no issues have been raised by the FTC and DOJ. The Company and Amneal have also filed a stipulation of dismissal with the court regarding the litigation. The Amneal settlement agreement provides for a full settlement and release by both the Company and Amneal of all claims that were or could have been asserted in the litigation and that arise out of the issues that were the subject of the litigation or Amneal's generic version of PENNSAID 2%.

Under the Amneal settlement agreement, the Company granted Amneal a non-exclusive license to manufacture and commercialize Amneal's generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Amneal's generic version of PENNSAID 2% during certain limited periods prior to the license effective date.

Under the Amneal settlement agreement, the license effective date is January 10, 2029; however, Amneal may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation or the entry of other third-party generic versions of PENNSAID 2%.

Under the Amneal settlement agreement, the Company also agreed not to sue or assert any claim against Amneal for infringement of any patent or patent application owned or controlled by the Company during the term of the license granted in Amneal settlement agreement based on the manufacture, use, sale, offer for sale, or importation of Amneal's generic version of PENNSAID 2% in the United States.

In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, the Company may be required to supply Amneal PENNSAID 2% as a non-exclusive, authorized distributor of generic PENNSAID 2%, with the Company receiving specified percentages of any net sales by Amneal. The Company also agreed that if it

enters into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, the Company will amend the Amneal settlement agreement to provide Amneal with terms that are no less favorable than those provided to the other parties.

The Company received from Apotex Inc. (“Apotex”) a Paragraph IV Patent Certification Notice Letter dated April 1, 2016, against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, 8,871,809, 9,066,913, 9,101,591, 9,132,110, 9,168,304, 9,168,305 and 9,220,784 advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%. The Company also received from Apotex a second Paragraph IV Patent Certification Notice Letter dated June 30, 2016, against Orange Book listed U.S. Patent Nos. 9,339,551 and 9,339,552, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%. The Company also received from Apotex a third Paragraph IV Patent Certification Notice Letter dated September 21, 2016, against Orange Book listed U.S. Patent No. 9,415,029, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%.

Currently, patent litigation is pending in the United States District Court for the District of New Jersey against four generic companies intending to market VIMOVO prior to the expiration of certain of the Company's patents listed in the Orange Book. These cases are in the United States District Court for the District of New Jersey. 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; (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, "Mylan"); and (iv) Actavis FL and Actavis Pharma, Inc. (collectively, "Actavis Pharma"). Patent litigation in the United States District Court for the District of New Jersey against a fifth generic company, Anchen Pharmaceuticals Inc. ("Anchen"), was dismissed on June 9, 2014 after Anchen recertified under Paragraph III. The Company understands that Dr. Reddy's has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy's is now able to commercialize VIMOVO under AstraZeneca's Nexium patent rights. The settlement agreement, however, has no effect on the 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 litigations that include 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 U.S. Patent Nos. 6,926,907, 8,557,285, 8,852,636, and 8,858,996 (the "'996 patent"). On June 18, 2015, the Company amended the complaints to add a charge of infringement of U.S. Patent No. 8,865,190 (the "'190 patent"). On January 7, 2016, Actavis Pharma asserted a counterclaim for declaratory judgment of invalidity and non-infringement of U.S. Patent No. 8,945,621 (the "'621 patent"). On January 25, 2016, the Company filed a new case against Actavis Pharma including allegations of infringement of U.S. Patent Nos. 9,161,920 and 9,198,888. This case was subsequently consolidated with the Actavis Pharma case involving the '996 patent, the '190 patent and U.S. Patent No. 8,852,636. On February 10, 2016, the Company amended the complaints against Dr. Reddy's, Lupin, and Mylan to add charges of infringement of U.S. Patent Nos. 9,161,920 and 9,198,888. On February 19, 2016, Mylan asserted a counterclaim for declaratory judgment of invalidity and non-infringement of U.S. Patent No. 9,220,698. On August 11, 2016, the Company filed new complaints asserting the '621 patent and U.S. Patent Nos. 9,220,698, and 9,345,695 against the defendants.

The cases asserting U.S. Patent Nos. 8,557,285 and 6,926,907 have been consolidated for discovery. The court has issued a claim construction order for these cases and set a trial date for December 7, 2016. On May 12, 2016, the court granted Dr. Reddy's motion for summary judgment of non-infringement of U.S. Patent No. 6,926,907 with respect to one of Dr. Reddy's two ANDAs.

The cases asserting the '996 patent, the '190 patent and U.S. Patent Nos. 8,852,636, 9,161,920 and 9,198,888 have been consolidated for discovery. The court has not issued a claim construction order or set a pretrial schedule.

On August 23, 2016, the court entered an order denying Mylan's motion to consolidate the cases asserting U.S. Patent Nos. 8,557,285 and 6,926,907 ("Case I") with the cases asserting the '996 patent, the '190 patent and U.S. Patent Nos. 8,852,636, 9,161,920, and 9,198,888 ("Case II"). The court ordered the parties to submit a proposed scheduling order for Case II no later than 14 days from the date of the order denying the motion to consolidate. On September 9, 2016, the VIMOVO Generics proposed a schedule for Case II while plaintiffs are seeking a stay of Case II pending the outcome of Case I at trial.

The Company understands the cases arise from Paragraph IV Patent Certification notice letters providing notice of the filing of ANDAs with the FDA seeking regulatory approval to market generic versions of VIMOVO before the expiration of the patents-in-suit. The Company understands the Dr. Reddy's notice letters were dated March 11, 2011, November 20, 2012 and April 20, 2015; the Lupin notice letters were dated June 10, 2011 and March 12, 2014;

the Mylan notice letters were dated May 16, 2013, February 9, 2015, January 26, 2016, February 26, 2016, July 19, 2016 and September 22, 2016; the Actavis Pharma notice letters were dated March 29, 2013, November 5, 2013, October 9, 2015, December 10, 2015, March 1, 2016, April 6, 2016, July 22, 2016 and September 8, 2016; and the Anchen notice letter was dated September 16, 2011.

On February 24, 2015, Dr. Reddy's filed a Petition for inter partes review ("IPR") of U.S. Patent No. 8,557,285, one of the patents in litigation in the above referenced VIMOVO cases. On October 9, 2015, the United States Patent and Trademark Office (the "U.S. PTO") denied such Petition for IPR.

On May 21, 2015, the Coalition for Affordable Drugs VII LLC ("Coalition for Affordable Drugs") filed a Petition for IPR of U.S. Patent No. 6,926,907, one of the patents in litigation in the above referenced VIMOVO cases. On December 8, 2015, the U.S. PTO denied such Petition for IPR.

On June 5, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of the '996 patent, one of the patents in litigation in the above referenced VIMOVO cases. On December 17, 2015, the U.S. PTO denied such Petition for IPR.

On August 7, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of U.S. Patent No. 8,852,636, one of the patents in litigation in the above referenced VIMOVO cases. On February 11, 2016, the U.S. PTO denied such Petition for IPR.

On August 12, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of the ’621 patent, one of the patents in litigation in the above referenced VIMOVO cases. On February 22, 2016, the Patent Trial and Appeal Board (the “PTAB”) issued a decision to institute the IPR. The PTAB hearing for the ‘621 patent is set for November 16, 2016. The PTAB must issue a final written decision on the IPR of the ’621 patent no later than February 22, 2017.

On August 19, 2015, Lupin filed Petitions for IPR of the ’996 patent, the ’190 patent and U.S. Patent No. 8,852,636, all patents in litigation in the above referenced VIMOVO cases. On March 1, 2016, the PTAB issued decisions to institute the IPRs for the ’996 patent” and the ’190 patent. On March 1, 2016, the PTAB denied the Petition for IPR for U.S. Patent No. 8,852,636. The PTAB hearings for the ‘996 patent and ‘190 patent are set for November 29, 2016. The PTAB must issue a final written decision on the IPRs of the ’996 patent and the ’190 patent no later than March 1, 2017.

On March 17, 2014, Hyperion received notice from Par Pharmaceutical, Inc. (“Par Pharmaceutical”) that it had filed 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, U.S. Patent No. 8,404,215, titled “Methods of therapeutic monitoring of nitrogen scavenging drugs,” which expires in March 2032 (the “’215 patent”), and U.S. Patent No. 8,642,012, titled “Methods of treatment using ammonia scavenging drugs,” which expires in September 2030 (the “’012 patent”), 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. Par Pharmaceutical did not challenge the validity, enforceability, or infringement of the Company’s primary composition of matter patent for RAVICTI, U.S. Patent No. 5,968,979 titled “Triglycerides and ethyl esters of phenylalkanoic acid and phenylalkanoic acid useful in treatment of various disorders,” which would have expired on February 7, 2015, but as to which Hyperion was granted an interim term of extension until February 7, 2016 and to which the U.S. PTO has granted a final term extension of 1,267 days. Hyperion filed suit in the United States District Court for the Eastern District of Texas, Marshall Division, against Par Pharmaceutical on April 23, 2014 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, and the Company has taken over and is responsible for this patent litigation. On September 15, 2015, the Company received notice from Par Pharmaceutical that it had filed a Paragraph IV Patent Certification alleging that U.S. Patent No. 9,095,559 (the “’559 patent”) is invalid and/or will not be infringed by Par Pharmaceutical’s manufacture, use or sale of the medicine for which the ANDA was submitted. On March 14, 2016, the Company received notice from Par Pharmaceutical that it had filed a Paragraph IV Patent Certification alleging that U.S. Patent No. 9,254,278 (the “’278 patent”) is invalid and/or will not be infringed by Par Pharmaceutical’s manufacture, use or sale of the medicine for which the ANDA was submitted. On June 3, 2016, the Company received notice from Par Pharmaceutical that it had filed a Paragraph IV Patent Certification alleging that U.S. Patent No. 9,326,966 (the “’966 patent”) is invalid and/or will not be infringed by Par Pharmaceutical’s manufacture, use or sale of the medicine for which the ANDA was submitted. 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 ’559 patent, the ’278 patent and the ’966 patent 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 court has not yet set a trial date for the Par New Jersey action.

On April 29, 2015, Par Pharmaceutical filed Petitions for IPR of the ’215 patent and the ’012 patent. The PTAB issued decisions instituting such IPRs on November 4, 2015. On December 14, 2015, the District Court Judge Roy Payne issued a stay pending a final written decision from the PTAB with respect to the IPRs of the ’215 patent and the ’012

patent. On September 29, 2016, the PTAB issued a final written decision holding all the claims of the ’215 patent unpatentable. The Company is considering whether to appeal the PTAB’s decision concerning the ’215 patent to the Federal Circuit. On November 3, 2016, the PTAB issued a final written decision holding all of the claims of the ‘012 patent patentable.

On September 4, 2015, the Company received notice from Lupin of Lupin's Paragraph IV Patent Certification against the '215 patent and the '012 patent, advising that Lupin had filed an ANDA with the FDA for a generic version of RAVICTI. On November 6, 2015, the Company also received Notice of Lupin's Paragraph IV Patent Certification against the '559 patent. Lupin has not advised the Company as to the timing or status of the FDA's review of its filing. On October 19, 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 the '215 patent, the '012 patent and the '559 patent 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. On April 6, 2016, the Company filed an Amended Complaint in the United States District Court for the District of New Jersey against Lupin alleging that Lupin has infringed the '559 patent by filing an ANDA seeking approval from the FDA to market generic versions of RAVICTI prior to expiration of the '559 patent. 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. On April 18, 2016, the Company received notice from Lupin of Lupin's Paragraph IV Patent Certification against the '278 patent. On July 6, 2016, the Company received notice from Lupin of Lupin's Paragraph IV Patent Certification against the '966 patent. The Company filed 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 the '278 patent and the '966 patent 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 court has not yet set a trial date for the Lupin New Jersey actions.

On April 1, 2016, Lupin filed a Petition to request an IPR of the '559 patent. On September 30, 2016, the PTAB issued a decision to institute the IPR for the '559 patent. The PTAB must issue a final written decision on the IPR of the '559 patent no later than September 30, 2017.

In November 2015, Express Scripts filed suit against the Company in Delaware Superior Court, Newcastle County, asserting claims for breach of contract, breach of the implied covenant of good faith and fair dealing, unjust enrichment, and declaratory relief arising from the parties' 2012 Preferred Savings Grid Rebate Program Agreement. The Company filed a counter-claim against Express Scripts for breach of contract, breach of the implied covenant of good faith and fair dealing, and declaratory relief arising from Express Scripts' breach of the rebate agreement. In September 2016, the Company entered into a settlement agreement and mutual release with Express Scripts pursuant to which the Company and Express Scripts were released from any and all claims relating to the litigation without admitting any fault or wrongdoing and the Company agreed to pay Express Scripts $65.0 million.

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 allege 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 allege that certain of the Company, the Director Defendants and the Underwriter Defendants violated sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended, (the "Securities Act") in connection with the Company's April 2015 public offering. The plaintiffs seek, among other things, an award of damages allegedly sustained by plaintiffs and the putative class, including a reasonable allowance for costs and attorneys' fees. The defendants' deadline to answer or otherwise respond to the amended consolidated complaint is November 14, 2016.

Between October 5 and October 7, 2016, two complaints (captioned Lavrenov v. Raptor Pharmaceutical Corp., et al., Case No. 16-cv-00901, and Jordan v. Raptor Pharmaceutical Corp., et al., Case No. 16-cv-00913) were filed in the United States District Court for the District of Delaware. Both actions were filed against Raptor and each member of Raptor's board of directors. The Company and Misneach Corporation, a wholly owned subsidiary of the Company, were named as defendants in the Lavrenov action, but not the Jordan action. The actions were brought by purported stockholders of Raptor, on their own behalf and as a putative class of Raptor stockholders, and assert causes of action under Sections 14 and 20 of the Securities Exchange Act of 1934, as amended. The Lavrenov action also asserts breach of fiduciary duty and aiding and abetting claims under Delaware law. The complaints allege, among other things, that the process leading up to the Raptor acquisition was inadequate and that the Schedule 14D-9 filed by Raptor with the Securities and Exchange Commission (the "SEC") omits certain material information, which allegedly renders the information disclosed materially misleading. The complaints seek, among other things, to enjoin the Raptor acquisition, or in the event the Raptor acquisition is consummated, to recover money damages. On October 17, 2016, Raptor filed an amended Schedule 14D-9 with the SEC. Plaintiffs did not file a motion to preliminarily enjoin the Raptor acquisition, which was completed on October 25, 2016.

NOTE 14 – DEBT AGREEMENTS

The Company's outstanding debt balances as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
2015 Term Loan Facility	$395,000	$ 398,000
2023 Senior Notes	475,000	475,000
Exchangeable Senior Notes	400,000	400,000
Total face value	1,270,000	1,273,000
Debt discount	(115,615)	(127,885)
Deferred financing fees	(7,161)	(8,359)
Total long-term debt	1,147,224	1,136,756
Less: current maturities	4,000	4,000
Long-term debt, net of current maturities	$1,143,224	$ 1,132,756

The Company adopted ASU No. 2015-03, Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs on January 1, 2016. The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. See Note 1 for further details of the impact this adoption has had on the financial statements.

2015 Senior Secured Credit Facility

On May 7, 2015, HPI, the Company and certain of its subsidiaries entered into a credit agreement with Citibank, N.A., as administrative and collateral agent, and the lenders from time to time party thereto (as amended by the 2016 Amendment described below in Note 18, the "credit agreement") providing for (i) the six-year $400.0 million term loan facility (the "2015 Term Loan Facility"); (ii) an uncommitted accordion facility subject to the satisfaction of certain financial and other conditions; and (iii) one or more uncommitted refinancing loan facilities with respect to loans thereunder (collectively the "2015 Senior Secured Credit Facility"). The initial borrower under the 2015 Term Loan Facility is HPI. The credit agreement allows for the Company and certain other subsidiaries of the Company to become borrowers under the accordion or refinancing facilities. Loans under the 2015 Term Loan Facility bear interest, at each borrower's option, at a rate equal to either the London Inter-Bank Offer Rate ("LIBOR"), plus an applicable margin of 3.5% per year (subject to a 1.0% LIBOR floor), or the adjusted base rate plus 2.5%. The adjusted base rate is defined as the greater of (a) LIBOR (using one-month interest period) plus 1%, (b) prime rate, (c) fed funds plus ½ of 1%, and (d) 2%. The Company borrowed the full $400.0 million available under the 2015 Term Loan Facility on May 7, 2015 as a LIBOR-based borrowing. In connection with the financing for the acquisition of Raptor, the credit agreement was amended to add a $375.0 million incremental term loan facility and change the interest rate margins applicable to the 2015 Term Loan Facility, as further described in Note 18.

The obligations under the credit agreement and any swap obligations and cash management obligations owing to a lender (or an affiliate of a lender) thereunder are and will be guaranteed by the Company and each of the Company's existing and subsequently acquired or organized 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 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 are permitted to make voluntary prepayments at any time without payment of a premium. HPI is required to make mandatory prepayments of loans under the 2015 Term Loan Facility (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) beginning with the fiscal year ending December 31, 2016, 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 and 1.75:1, respectively). The loans under the 2015 Term Loan Facility will amortize in equal quarterly installments in an aggregate annual amount equal to 1% of the original principal amount thereof, with any remaining balance payable on the final maturity date of the loans under the 2015 Term Loan Facility.

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, and customary events of default.

The Company was, as of September 30, 2016, and is currently in compliance with this credit agreement.

As of September 30, 2016, the fair value of the 2015 Term Loan Facility was approximately $391.1 million, categorized as a Level 2 instrument, as defined in Note 11.

See Note 18 for further details on changes to the 2015 Senior Secured Credit Facility.

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, and in offshore transactions to non-U.S. persons in reliance on Regulation S under the Securities Act.

In connection with the closing of the Hyperion acquisition 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 and the Company and all of the Company's direct and indirect subsidiaries that are guarantors under the 2015 Senior Secured Credit Facility fully and unconditionally guaranteed on a senior unsecured basis HPI's obligations under the 2023 Senior Notes.

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 exchanged, repurchased or redeemed.

Except as described below, the 2023 Senior Notes may not be redeemed before May 1, 2018. Thereafter, 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. At any time prior to May 1, 2018, some or all of the 2023 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 May 1, 2018, up to 35% of the aggregate principal amount of the 2023 Senior Notes may be redeemed at a redemption price of 106.625% of the aggregate principal amount thereof, plus accrued and unpaid interest, with the net proceeds of certain equity offerings. 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 also includes customary events of default.

The Company was, as of September 30, 2016, and is currently in compliance with the indenture governing the 2023 Senior Notes.

As of September 30, 2016, the fair value of the 2023 Senior Notes was approximately $446.5 million, categorized as a Level 2 instrument, as defined in Note 11.

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 several 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 20 trading days whether or not consecutive) during any 30 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 ending on June 30, 2015 (and only during such calendar quarter), if the last reported sale price of ordinary shares of the Company for at least 20 trading days (whether or not consecutive) during the period of 30 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 September 30, 2016, 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 Topic ASC 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 September 30, 2016, the fair value of the Exchangeable Senior Notes was approximately $386.8 million, categorized as a Level 2 instrument, as defined in Note 11.

2014 Senior Secured Credit Facility

On June 17, 2014, the Company entered into a credit agreement with a group of lenders and Citibank, N.A., as administrative and collateral agent to provide the Company with $300.0 million in financing through a five-year senior secured credit facility (the “2014 Senior Secured Credit Facility”). Loans under the five-year $300.0 million term loan facility (“2014 Term Loan Facility”) bore interest, at each borrower’s option, at a rate equal to either the LIBOR, plus an applicable margin of 8.0% per year (subject to a 1.0% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 7.0% per year. The Company borrowed the full $300.0 million available on the 2014 Term Loan Facility on September 19, 2014 as a LIBOR-based borrowing.

On May 7, 2015, the Company repaid the entire $300.0 million outstanding amount under the 2014 Senior Secured Credit Facility in connection with the closing of the Hyperion acquisition and recognized a $56.8 million loss on debt extinguishment as a result of the early repayment.

Convertible Senior Notes

On November 22, 2013, the Company issued $150.0 million aggregate principal amount of 5.00% Convertible Senior Notes due 2018 (“Convertible Senior Notes”), and received net proceeds of $143.6 million, after deducting fees and expenses of $6.4 million.

During 2015, the Company entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes ("2015 Conversions") which were on substantially the same terms as prior conversion agreements entered into by the Company. Under the 2015 Conversions, the applicable holders agreed to convert an aggregate principal amount of $61.0 million of Convertible Senior Notes held by them and the Company agreed to settle such conversions by issuing an aggregate of 11,368,921 ordinary shares. In addition, pursuant to such conversion agreements, the Company made an aggregate cash payment of $10.0 million to the applicable holders for additional exchange consideration and $0.9 million for accrued and unpaid interest, and recognized a non-cash charge of $10.1 million related to the extinguishment of debt as a result of the note conversions. Following the closings under the 2015 Conversions, there were no Convertible Senior Notes remaining outstanding.

NOTE 15 – SHAREHOLDERS' EQUITY

During the nine months ended September 30, 2016, the Company issued an aggregate of:

- 496,012 ordinary shares in connection with the exercise of stock options and received $3.4 million in proceeds;
- 619,696 ordinary shares in net settlement of vested restricted stock units;
- 13,584 ordinary shares in net settlement of vested performance stock units; and
- 261,780 ordinary shares pursuant to employee stock purchase plans and received $3.2 million in proceeds.

During the nine months ended September 30, 2016, warrants to purchase an aggregate of 207,110 ordinary shares of the Company were exercised in cashless exercises, resulting in the issuance of 161,259 ordinary shares. As of September 30, 2016, there were outstanding warrants to purchase 1,374,410 ordinary shares of the Company.

During the nine months ended September 30, 2016, the Company made payments of $5.3 million for employee withholding taxes relating to share-based awards.

In May 2016, the Company's board of directors authorized a share repurchase program pursuant to which the Company may repurchase up to 5,000,000 of its ordinary shares. The timing and amount of repurchases, including whether the Company decides to repurchase any shares pursuant to the authorization, will depend on a variety of factors, including the price of the Company's ordinary shares, alternative investment opportunities, the Company's cash resources, restrictions under the Company's credit agreement, and market conditions. As of September 30, 2016, the Company had not purchased any of its ordinary shares under this repurchase program.

NOTE 16 – SHARE-BASED INCENTIVE PLANS

Employee Stock Purchase Plan

2014 Employee Stock Purchase Plan. On May 17, 2014, HPI's board of directors adopted the 2014 Employee Stock Purchase Plan (the "2014 ESPP"). On September 18, 2014, at a special meeting of the stockholders of HPI (the "Special Meeting"), HPI's stockholders approved the 2014 ESPP. Upon consummation of the Vidara Merger, the Company

assumed the 2014 ESPP. As described below, effective as of May 3, 2016, the number of ordinary shares authorized for issuance under the 2014 ESPP was reduced by 5,000,000 shares.

As of September 30, 2016, an aggregate of 4,076,279 ordinary shares were authorized and available for future issuance under the 2014 ESPP.

Share-Based Compensation Plans

2005 Stock Plan. In October 2005, HPI adopted the 2005 Stock Plan (the "2005 Plan"). Upon the signing of the underwriting agreement related to HPI's initial public offering, on July 28, 2011, no further option grants were made under the 2005 Plan. All stock awards granted under the 2005 Plan prior to July 28, 2011 continue to be governed by the terms of the 2005 Plan. Upon consummation of the Vidara Merger, the Company assumed the 2005 Plan.

2011 Equity Incentive Plan. In July 2010, HPI's board of directors adopted the 2011 Equity Incentive Plan (the "2011 EIP"). In June 2011, HPI's stockholders approved the 2011 EIP, and it became effective upon the signing of the underwriting agreement related to HPI's initial public offering on July 28, 2011. Upon consummation of the Vidara Merger, the Company assumed the 2011 EIP, and upon the effectiveness of the Horizon Pharma Public Limited Company 2014 Equity Incentive Plan (the "2014 EIP"), no additional stock awards were or will be made under the 2011 Plan, although all outstanding stock awards granted under the 2011 Plan continue to be governed by the terms of the 2011 Plan.

2014 Equity Incentive Plan and 2014 Non-Employee Equity Plan. On May 17, 2014, HPI's board of directors adopted the 2014 EIP and the Horizon Pharma Public Limited Company 2014 Non-Employee Equity Plan (the "2014 Non-Employee Equity Plan"). At the Special Meeting, HPI's stockholders approved the 2014 EIP and 2014 Non-Employee Equity Plan. Upon consummation of the Vidara Merger, the Company assumed the 2014 EIP and 2014 Non-Employee Equity Plan, which serve as successors to the 2011 EIP.

The 2014 EIP provides for the grant of incentive and nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other stock awards that may be settled in cash, shares or other property to the employees of the Company (or a subsidiary company). The number of ordinary shares of the Company that were initially authorized for issuance under the 2014 EIP was no more than 22,052,130, which number consisted of (i) 15,500,000 ordinary shares of the Company; plus (ii) the number of shares available for issuance pursuant to the grant of future awards under the 2011 EIP; plus (iii) any shares subject to outstanding stock awards granted under the 2011 EIP and the 2005 Plan that expire or terminate for any reason prior to exercise or settlement or are forfeited, redeemed or repurchased because of the failure to meet a contingency or condition required to vest such shares; less (iv) 10,000,000 shares, which is the additional number of shares which were previously approved as an increase to the share reserve of the 2011 EIP. On March 23, 2015, the compensation committee of the Company's board of directors approved amending the 2014 EIP subject to shareholder approval to, among other things, increase the aggregate number of shares authorized for issuance under the 2014 EIP by an additional 14,000,000 shares. On May 6, 2015, the shareholders of the Company approved such amendment to the 2014 EIP. On February 25, 2016, the compensation committee of the Company's board of directors approved, subject to shareholder approval, amending the 2014 EIP to, among other things, increase the aggregate number of shares authorized for issuance under the 2014 EIP beyond those remaining available for future grant under the 2014 EIP by an additional 6,000,000 shares and also approved a reduction in the number of shares authorized under our 2014 Non-Employee Equity Plan and 2014 ESPP by 1,000,000 shares and 5,000,000 shares, respectively, contingent on shareholder approval of the amendment to the 2014 EIP. On May 3, 2016, the shareholders of the Company approved the amendment to the 2014 EIP. The Company's board of directors has authority to suspend or terminate the 2014 EIP at any time.

The 2014 Non-Employee Equity Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other forms of stock awards that may be settled in cash, shares or other property to the non-employee directors and consultants of the Company (or a subsidiary company). The total number of ordinary shares of the Company that were initially authorized for issuance under the 2014 Non-Employee Equity Plan is 2,500,000. As described above, effective as of May 3, 2016, the number of ordinary shares authorized for issuance under the 2014 Non-Employee Equity Plan was reduced by 1,000,000 shares. The Company's board of directors has authority to suspend or terminate the 2014 Non-Employee Equity Plan at any time.

As of September 30, 2016, an aggregate of 7,442,963 and 963,567 ordinary shares were authorized and available for future grants under the 2014 EIP and 2014 Non-Employee Equity Plan, respectively.

Stock Options

The following table summarizes stock option activity during the nine months ended September 30, 2016:

	Options	Weighted Average	Weighted Average	Aggregate Intrinsic Value

		Exercise Price	Contractual Term Remaining (in years)	(in thousands)
Outstanding as of December 31, 2015	13,385,791	$ 17.73		
Granted	1,741,192	$ 18.13		
Exercised	(496,012)	$ 6.89		
Forfeited	(1,012,082)	$ 18.02		
Expired	(58,879)	$ 12.00		
Outstanding as of September 30, 2016	13,560,010	$ 18.18	7.79	$ 46,036
Exercisable as of September 30, 2016	6,393,796	$ 15.20	6.88	$ 36,202

Stock options typically have a contractual term of 10 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 nine months ended September 30, 2016 and 2015, and assumptions used to value stock options, are as follows:

	For the Nine Months Ended September 30,	
	2016	2015
Dividend yield	—	—
Risk-free interest rate	1.3% - 1.8%	1.3% - 2.0%
Weighted average expected volatility	73.8%	77.1%
Expected life (in years)	6.1	6.0
Weighted average grant-date fair value per share of options granted	$ 11.78	$ 16.20

Dividend yield

The Company has never paid dividends and does not anticipate paying any dividends in the near future. Additionally, the 2015 Senior Secured Credit Facility, as amended by the 2016 Amendment (described in Note 14 above and Note 18 below), as well as the 2023 Senior Notes and the 2024 Senior Notes (described in Note 18 below), 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. ASC Topic 718, Compensation-Stock Compensation ("ASC 718") requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Restricted Stock Units

The following table summarizes restricted stock unit activity for the nine months ended September 30, 2016:

	Number of Units	Weighted Average Grant-Date Fair Value Per Unit
Outstanding as of December 31, 2015	3,361,746	$ 18.71
Granted	763,519	$ 17.09
Vested	(910,322)	$ 17.40
Forfeited	(329,428)	$ 17.71
Outstanding as of September 30, 2016	2,885,515	$ 18.80

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

Performance Stock Units

The following table summarizes performance stock unit ("PSU") activity for the nine months ended September 30, 2016:

	Number of Units	Weighted Average Grant-Date Fair Value Per Unit	Average Illiquidity Discount	Recorded Weighted Average Fair Value Per Unit
Outstanding as of December 31, 2015	13,049,000			
Granted	260,000	$ 7.99	8.2 %	$ 7.34
Vested	(20,000)	$ 18.97	0.0 %	$ 18.97
Forfeited	(960,000)	$ 14.32	14.5 %	$ 12.25
Outstanding as of September 30, 2016	12,329,000			

In January 2016, the compensation committee of the Company's board of directors approved the grant of 260,000 PSUs to certain members of the Company's senior leadership team.

In 2014, the Company granted 25,000 PSUs. All other outstanding PSUs were granted in 2015 and 2016 and may vest if the Company's total compounded annual shareholder rate of return ("TSR") over three performance measurement periods summarized below equals or exceeds a minimum of 15%.

Vesting Tranche	Percent of Total PSU Award	Beginning of Performance Measurement Period	End of Performance Measurement Period	Length of Performance Measurement Period (Years)
Tranche One	33.3 %	March 23, 2015	December 22, 2017	2.75
Tranche Two	33.3 %	March 23, 2015	March 22, 2018	3.00
Tranche Three	33.3 %	March 23, 2015	June 22, 2018	3.25

These outstanding PSUs granted in 2015 and 2016 will vest in amounts ranging from 25% to 100% based on the achievement of the following TSR over the three performance periods:

TSR Achieved	Vesting Amount	
15%	25	%
30%	50	%
45%	75	%
60%	100	%

The TSR will be based on the volume weighted average trading price ("VWAP") of the Company's ordinary shares over the 20 trading days ending on the last day of each of the three performance measurement periods versus the VWAP of the Company's ordinary shares over the 20 trading days ended March 23, 2015 of $21.50. These PSUs are subject to a post vesting holding period of one year for 50% of the PSUs and two years for 50% of the PSUs for those who were members of the executive committee at the date of grant, and one year for 50% of the PSUs for all others who were not executive committee members at the date of grant.

The Company accounts for the PSUs as equity-settled awards in accordance with ASC 718. Because the value of the outstanding PSUs granted in 2015 and 2016 is 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 PSUs. As a result, the Monte Carlo model is applied and the most significant valuation assumptions used include:

	For the Nine Months Ended September 30,	
	2016	2015
Valuation date stock price	$17.72 - 21.07	$22.77 - 35.06
Expected volatility	76.8% - 77.6%	64.6% - 67.3%
Risk free rate	1.0% - 1.2%	1.0% - 1.1%

The average estimated fair value of each outstanding PSU granted under the 2014 EIP is as follows (allocated between groupings based on grant-date classification):

	Number of Units	Weighted Average Fair Value Per Unit	Average Illiquidity Discount	Recorded Weighted Average Fair Value Per Unit
Executive committee members	9,173,000	$ 15.18	18.3 %	$ 12.40
Non-executive committee members	3,131,000	$ 13.55	7.3 %	$ 12.56
	12,304,000	$ 14.76	15.7 %	$ 12.44

During the nine months ended September 30, 2016, the Company recorded $36.1 million of expense related to PSUs.

Cash Long-Term Incentive Program

On November 5, 2014, the compensation committee of the Company's board of directors approved a performance cash long-term incentive program for the members of the Company's executive committee and executive leadership team, including its executive officers (the "Cash Bonus Program"). Participants in the Cash Bonus Program will be eligible for a specified cash bonus. The Cash Bonus Program pool funding of approximately $16.0 million was determined based on the Company's actual TSR over the period from November 5, 2014 to May 6, 2015, and the bonus will be earned and payable only if the TSR for the period from November 5, 2014 to November 4, 2017 is greater than 15%. The portion of the total bonus pool payable to individual participants is based on allocations established by the Company's compensation committee. Participants must remain employed by the Company through November 4, 2017 unless a participant's earlier departure from employment is due to death, disability, termination without cause or a change in control transaction. Bonus payments under the Cash Bonus Program, if any, will be made after November 4, 2017.

The Company accounts for the Cash Bonus Program under the liability method in accordance with ASC 718. Because vesting of the bonus pool is dependent upon the attainment of a VWAP of $18.37 or higher over the 20 trading days ending November 4, 2017, the Cash Bonus Program will be considered to be subject to a "market condition" for the purposes of ASC 718. ASC 718 requires the impact of the market condition to be considered when estimating the fair value of the bonus pool. As a result, the Monte Carlo simulation model is applied and the fair value is revalued at each reporting period. As of September 30, 2016 and December 31, 2015, the estimated fair value was $5.1 million and $6.0 million, respectively. For the nine months ended September 30, 2016, the Company recorded an expense of $0.9 million to the unaudited condensed consolidated statement of comprehensive loss as a result of the valuation of the Cash Bonus Program. The most significant valuation assumptions used as of September 30, 2016 include:

- Valuation Date Stock Price - $18.13.
- Expected Volatility - The expected volatility assumption of 88.0% is based on the Company's historical volatility over the 1.09 year period ending September 30, 2016, based upon daily stock price observations.
- Risk Free Rate – 0.60%, which is based upon the yield on U.S. Treasury Separate Trading of Registered Interest and Principal Securities with a remaining term of 1.09 years as of September 30, 2016.

Share-Based Compensation Expense

The following table summarizes share-based compensation expense included in the Company's condensed consolidated statements of operations for the nine months ended September 30, 2016 and 2015 (in thousands):

	For the Nine Months Ended September 30,	
	2016	2015
Research and development	$ 6,845	$ 4,712
Sales and marketing	19,306	15,571
General and administrative	58,770	37,513
Total share-based compensation expense	$ 84,921	$ 57,796

No material income tax benefit has been recognized relating to share-based compensation expense and no tax benefits have been realized from exercised stock options, due to the Company's net loss position. As of September 30, 2016, the Company estimates that pre-tax unrecognized compensation expense of $220.5 million for all unvested share-based awards, including stock options, restricted stock units and PSUs, will be recognized through the third quarter of 2020. 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.

NOTE 17 – 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. 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 (benefit) expense for income taxes for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
(Loss) income before (benefit) expense for income taxes	$ (33,617)	$ 25,256	$ (68,238)	$ (121,250)
(Benefit) expense for income taxes	(27,747)	21,979	(31,946)	(136,788)
Net (loss) income	$ (5,870)	$ 3,277	$ (36,292)	$ 15,538

In the course of preparing the condensed consolidated balance sheet and the condensed consolidated statements of comprehensive loss as of and for the three and nine months ended September 30, 2016, the Company determined that deferred tax liabilities were understated by $2.4 million and accrued expenses were understated by $1.1 million, each as of December 31, 2015, and the benefit for income taxes was overstated by $3.5 million for the year ended December 31, 2015. The Company concluded that these misstatements were not material, individually or in the aggregate, to any of the reporting periods. As such, the correction for this error was made during the three months ended September 30, 2016.

During the three and nine months ended September 30, 2016, the Company recorded a benefit for income taxes of $27.7 million and $31.9 million, respectively, compared to an expense of $22.0 million and a benefit of $136.8 million during the three and nine months ended September 30, 2015, respectively. The benefit for income taxes recorded during the three and nine months ended September 30, 2016 was attributable to pre-tax losses incurred in higher tax rate jurisdictions which exceeded pre-tax income in lower tax rate jurisdictions during the periods, as well as certain discrete factors and events, including the tax benefit recorded as a result of the $65.0 million litigation settlement with Express Scripts. The benefit for income taxes recorded during the nine months ended September 30, 2015 was primarily attributable to the release of valuation allowances in the United States due to the recognition of significant deferred tax liabilities as a result of the Hyperion acquisition as well as the ability to recognize a tax benefit for the Company’s U.S. tax consolidation group losses then projected to be incurred during 2015.

Deferred tax assets and liabilities arise from acquisition accounting adjustments where book values of certain assets and liabilities differ from their tax bases. 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.

NOTE 18 – SUBSEQUENT EVENTS

Raptor Acquisition

On October 25, 2016, the Company completed its acquisition of Raptor pursuant to which the Company acquired all of the issued and outstanding shares of Raptor common stock at a price of $9.00 per share in cash or approximately $804.7 million on a fully diluted basis. The Raptor acquisition expands the Company's product portfolio by adding two orphan disease medicines, PROCYSBI and QUINSAIR.

In connection with the Raptor acquisition, the Company expects to pay an estimated $19.2 million of transaction fees for legal, advisory and other fees.

The final determination of the purchase price allocation is expected to be completed as soon as practicable after consummation of the Raptor acquisition. Due to the limited time between the acquisition date and the filing of this Quarterly Report on Form 10-Q, it is not practicable for the Company to disclose: (i) the allocation of purchase price to assets acquired and liabilities assumed as of the date of close, and (ii) pro forma revenues and earnings of the combined company for the period ended September 30, 2016.

2024 Senior Notes

On October 25, 2016, HPI and Horizon Pharma USA, Inc., a wholly-owned subsidiary of the Company ("HPUSA" and, together with HPI, the "2024 Issuers"), completed a private placement of $300.0 million aggregate principal amount of 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 2024 Senior Notes are the 2024 Issuers' general unsecured senior obligations and the Company and all of the Company's direct and indirect subsidiaries that are guarantors under the 2015 Senior Secured Credit Facility and the 2016 Incremental Loan Facility (as defined below) fully and unconditionally guaranteed on a senior unsecured basis the 2024 Issuers' obligations under the 2024 Senior Notes.

The 2024 Senior Notes accrue interest at an annual rate of 8.75% 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 exchanged, 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.

2016 Amendment to Credit Agreement

On October 25, 2016, HPI and HPUSA (together, in such capacity, the "Incremental Borrowers") entered into an amendment to the credit agreement (the "2016 Amendment") with Citibank, N.A., as administrative and collateral agent, and Bank of America, N.A., as the incremental B-1 lender thereunder, pursuant to which the Incremental Borrowers borrowed $375.0 million aggregate principal amount of loans (the "2016 Incremental Loan Facility"). The 2016

Incremental Loan Facility was incurred as a separate class of term loans under the credit agreement with the same terms of loans under the 2015 Term Loan Facility, except as described below.

Loans under the 2016 Incremental Loan Facility bear interest, at each Incremental Borrowers' option, at a rate equal to either LIBOR plus an applicable margin of 4.50% per year (subject to a LIBOR floor of 1.0%), or the adjusted base rate plus 3.50%. The terms of the loans under the 2015 Term Loan Facility (the "2015 Loans") provided for an amendment such that the effective yield of the 2015 Loans would not be less than the effective yield of the loans under the 2016 Incremental Loan Facility (the "Incremental Loans") minus 0.50%. Consequently, the issuance of the Incremental Loans resulted in an increase of the interest rate applicable to the 2015 Loans, as of October 25, 2016, to LIBOR plus 4.00%, subject to a LIBOR floor of 1.0% (an initial interest rate of 5.00%). 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, except that with respect to the Incremental Loans, a 1% premium will apply to a repayment of the Incremental Loans in connection with a repricing of, or any amendment to the credit agreement in a repricing of, such loans effected on or prior to the date that is twelve months following October 25, 2016.

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.

OVERVIEW

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, including its predecessor, Horizon Pharma, Inc., or HPI. All references to "Vidara" are references to Horizon Pharma plc (formerly known as Vidara Therapeutics International Public Limited Company) and its consolidated subsidiaries prior to the effective time of the merger of the businesses of HPI and Vidara on September 19, 2014, or the Vidara Merger. The disclosures in this report relating to the pre-Vidara Merger business of Horizon Pharma plc, unless noted as being the business of Vidara prior to the Vidara Merger, pertain to the business of HPI prior to the Vidara Merger.

OUR BUSINESS

We are a biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs. We market eleven medicines through our orphan, rheumatology and primary care business units. Our marketed medicines are ACTIMMUNE® (interferon gamma-1b), BUPHENYL® (sodium phenylbutyrate) Tablets and Powder, DUEXIS® (ibuprofen/famotidine), KRYSTEXXA® (pegloticase), MIGERGOT® (ergotamine tartrate & caffeine suppositories), PENNSAID® (diclofenac sodium topical solution) 2% w/w, or PENNSAID 2%, PROCYSBI® (cysteamine bitartrate) delayed-release capsules, QUINSAIR™ (aerosolized form of levofloxacin), RAVICTI® (glycerol phenylbutyrate) Oral Liquid, RAYOS® (prednisone) delayed-release tablets and VIMOVO® (naproxen/esomeprazole magnesium).

We developed DUEXIS and RAYOS, known as LODOTRA® outside the United States, acquired the U.S. rights to VIMOVO from AstraZeneca AB in November 2013, acquired certain rights to ACTIMMUNE as a result of the Vidara Merger in September 2014, acquired the U.S. rights to PENNSAID 2% from Nuvo Research Inc. in October 2014, acquired RAVICTI and BUPHENYL, known as AMMONAPS® in certain European countries, as a result of our acquisition of Hyperion Therapeutics Inc., or Hyperion, in May 2015, acquired KRYSTEXXA and the U.S. rights to MIGERGOT as a result of our acquisition of Crealta Holdings LLC., or Crealta, in January 2016 and acquired PROCYSBI and QUINSAIR as a result of our acquisition of Raptor Pharmaceutical Corp., or Raptor, in October 2016.

On May 18, 2016, we entered into a definitive agreement with Boehringer Ingelheim International GmbH, or Boehringer Ingelheim International, to acquire certain rights to interferon gamma-1b, which Boehringer Ingelheim International currently commercializes under the trade names IMUKIN®, IMUKINE®, IMMUKIN® and IMMUKINE® in an estimated 30 countries primarily in Europe and the Middle East. Under the terms of the agreement, we paid Boehringer Ingelheim International €5.0 million ($5.6 million when converted using a Euro-to-Dollar exchange rate of 1.1132) upon signing and will pay €20.0 million upon closing, for certain rights for interferon gamma-1b in all territories outside of the United States, Canada and Japan, as we currently hold marketing rights to interferon gamma-1b in these territories. We currently market interferon gamma-1b as ACTIMMUNE in the United States. The transaction is expected to close in the first half of 2017 and we are continuing to work with Boehringer Ingelheim International to enable the transfer of applicable marketing authorizations. Under the terms of a separate agreement, we also in-licensed certain U.S., European and Canadian intellectual property rights for interferon gamma-1b for the treatment of Friedreich's ataxia, or FA, a degenerative neuro-muscular disorder. Interferon gamma-1b is currently not indicated or approved for the treatment of FA.

In February 2015, we submitted an investigational new drug application to the U.S. Food and Drug Administration for ACTIMMUNE in the treatment of FA. In June 2015, we commenced the Phase 3 Safety, Tolerability and Efficacy of ACTIMMUNE Dose Escalation in Friedreich's Ataxia Study, or STEADFAST study, of ACTIMMUNE for the treatment of FA. Top-line results from the STEADFAST study are expected in late December 2016, at which time we will make a determination on the next steps for the development of ACTIMMUNE in the treatment of FA.

On October 25, 2016, we completed our acquisition of Raptor in which we acquired all of the issued and outstanding shares of Raptor's common stock for $9.00 per share in cash, or approximately $804.7 million on a fully-diluted basis. Following completion of the acquisition, Raptor became our wholly owned subsidiary and converted to a Delaware limited liability company, changing its name to Horizon Pharmaceutical LLC. We financed the transaction through $300.0 million aggregate principal amount of 8.75% Senior Notes due 2024, or the 2024 Senior Notes, $375.0 million aggregate principal amount of loans pursuant to an amendment to our existing credit agreement and cash on hand.

Our medicines are dispensed by retail and specialty pharmacies. Part of our commercial strategy for our primary care and rheumatology business units is to offer physicians the opportunity to have their patients fill prescriptions through pharmacies participating in our HorizonCares patient access program. This program does not involve us in the prescribing of medicines. The purpose of this program is solely to assist in ensuring that, when physicians determine that one of our medicines offers a potential clinical benefit to their patients and prescribe the medicine for an eligible patient, financial assistance may be available to reduce a commercial patient's out-of-pocket costs. In the first nine months of 2016, this resulted in 99.9 percent of commercial patients having co-pay amounts of $10 or less when filling prescriptions for our medicines utilizing our patient access program. For commercial patients who are prescribed our primary care medicines or RAYOS, the HorizonCares program offers co-pay assistance when a third-party payer covers a prescription but requires an eligible patient to pay a co-pay or deductible, and offers full subsidization when a third-party payer rejects coverage for an eligible patient. For patients who are prescribed our orphan medicines, our patient access programs provide reimbursement support, a clinical nurse program, co-pay and other patient assistance. The aggregate commercial value of our patient access programs for the nine months ended September 30, 2016 was $1,275.2 million. All pharmacies that dispense prescriptions for our medicines, which we estimate to be about 20,000 during the first nine months of 2016, are fully independent, including those that participate in HorizonCares. We do not own or possess any option to purchase an ownership stake in any pharmacy that distributes our medicines, and our relationship with each pharmacy is non-exclusive and arm's length. All of our medicines are dispensed through pharmacies independent of our business.

As an alternative means of ensuring access to our medicines, we have also begun pursuing business arrangements with pharmacy benefit managers, or PBMs, and other payers to secure formulary status and reimbursement of our medicines, such as our recently announced arrangements with CVS Caremark and Prime Therapeutics LLC. While we believe that, if successful, this strategy would result in broader inclusion of certain of our primary care medicines on healthcare plan formularies, and therefore increase payer reimbursement and lower our cost of providing patient access programs, these arrangements generally require us to pay administrative and rebate payments to the PBMs and/or other payers.

We have a compliance program in place to address adherence with various laws and regulations relating to the selling, marketing and manufacturing of our medicines, as well as certain third-party relationships, including pharmacies. Specifically with respect to pharmacies, the compliance program utilizes a variety of methods and tools to monitor and audit pharmacies, including those that participate in our patient access programs, to confirm their activities, adjudication and practices are consistent with our compliance policies and guidance.

We market our medicines in the United States through our field sales force, which numbered approximately 470 representatives as of September 30, 2016. Our strategy is to use the commercial strength and infrastructure we have established in creating a global biopharmaceutical company to continue the successful commercialization of our existing medicine portfolio while also expanding and leveraging these capabilities by identifying, developing, acquiring and commercializing additional differentiated and accessible medicines that address unmet medical needs.

RESULTS OF OPERATIONS

Comparison of Three Months Ended September 30, 2016 and 2015

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 September 30, 2016, compared to the three months ended September 30, 2015.

	For the Three Months Ended September 30,		Increase / (Decrease)
	2016	2015	
	(in thousands)		
Net sales	$208,702	$226,544	$ (17,842)
Cost of goods sold	85,161	61,250	23,911
Gross profit	123,541	165,294	(41,753)
Operating expenses:			
Research and development	12,814	13,073	(259)
Sales and marketing	72,564	51,973	20,591
General and administrative	59,485	54,516	4,969
Total operating expenses	144,863	119,562	25,301
Operating (loss) income	(21,322)	45,732	(67,054)
Other income (expense), net:			
Interest expense, net	(19,066)	(20,300)	(1,234)
Foreign exchange loss	(108)	(86)	22
Other income (expense), net	6,879	(90)	(6,969)
Total other income (expense), net	(12,295)	(20,476)	(8,181)
(Loss) income before (benefit) expense for income taxes	(33,617)	25,256	58,873
(Benefit) expense for income taxes	(27,747)	21,979	49,726
Net (loss) income	$(5,870)	$3,277	$ (9,147)

Net sales. Net sales decreased $17.8 million, or 7.9%, to $208.7 million during the three months ended September 30, 2016, from $226.5 million during the three months ended September 30, 2015. Excluding the $65.0 million litigation settlement with Express Scripts, Inc., or Express Scripts, as discussed further below, non-GAAP adjusted net sales increased by $47.2 million, or 20.8%, from the same quarter in the prior year.

The following table presents a summary of total net sales attributed to geographic sources for the three months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30, 2016		Three Months Ended September 30, 2015	
	Amount	% of Total Net Sales	Amount	% of Total Net Sales
United States	$ 204,302	98 %	$ 223,381	99 %
Rest of world	4,400	2 %	3,163	1 %
Total Net Sales	$ 208,702		$ 226,544	

The following table reflects the components of net sales for the three months ended September 30, 2016 and 2015:

	Three Months Ended			
	September 30,		Change	Change
	2016	2015	$	%
	(in thousands)			
PENNSAID 2%	$80,199	$43,892	$36,307	83 %
DUEXIS	47,615	56,902	(9,287)	(16 %)
RAVICTI	42,176	33,427	8,749	26 %
VIMOVO	32,839	46,855	(14,016)	(30 %)
KRYSTEXXA	25,542	—	25,542	*
ACTIMMUNE	24,915	28,737	(3,822)	(13 %)
RAYOS	13,419	11,670	1,749	15 %
BUPHENYL	4,341	3,962	379	10 %
LODOTRA	1,502	1,099	403	37 %
MIGERGOT	1,154	—	1,154	*
Litigation settlement	(65,000)	—	(65,000)	*
Total Net Sales	$208,702	$226,544	$(17,842)	(8 %)

*Percentage change is not meaningful.

The decrease in net sales during the three months ended September 30, 2016 was primarily due to the $65.0 million litigation settlement with Express Scripts, along with decreases in net sales of DUEXIS and VIMOVO, offset by growth in net sales of PENNSAID 2% and RAVICTI and the recognition of KRYSTEXXA sales following the acquisition of Crealta in January 2016.

PENNSAID 2%. Net sales increased $36.3 million, or 83%, to $80.2 million during the three months ended September 30, 2016, from $43.9 million during the three months ended September 30, 2015. Net sales increased by approximately $24.0 million due to higher net pricing and $12.3 million resulting from prescription volume growth.

DUEXIS. Net sales decreased $9.3 million, or 16%, to $47.6 million during the three months ended September 30, 2016, from $56.9 million during the three months ended September 30, 2015. Net sales decreased by approximately $17.5 million due to lower net pricing resulting from higher co-pay and other patient assistance, offset by an increase of approximately $8.2 million resulting from prescription volume growth.

RAVICTI. Net sales increased $8.8 million, or 26%, to $42.2 million during the three months ended September 30, 2016, from $33.4 million during the three months ended September 30, 2015. Net sales increased by approximately $7.6 million resulting from prescription volume growth and $1.2 million due to higher net pricing.

VIMOVO. Net sales decreased $14.0 million, or 30%, to $32.8 million during the three months ended September 30, 2016, from $46.8 million during the three months ended September 30, 2015. Net sales decreased by approximately $7.6 million due to lower net pricing resulting from higher co-pay and other patient assistance, and approximately $6.4 million resulting from prescription volume decreases.

KRYSTEXXA. Net sales were $25.5 million during the three months ended September 30, 2016. We began recognizing KRYSTEXXA sales following the acquisition of Crealta in January 2016.

ACTIMMUNE. Net sales decreased $3.8 million, or 13%, to $24.9 million during the three months ended September 30, 2016, from $28.7 million during the three months ended September 30, 2015. Net sales decreased by approximately $3.3 million resulting from prescription volume decreases and approximately $0.5 million due to lower net pricing resulting from higher co-pay and other patient assistance.

RAYOS. Net sales increased $1.7 million, or 15%, to $13.4 million during the three months ended September 30, 2016, from $11.7 million during the three months ended September 30, 2015. Net sales increased by approximately $2.4 million resulting from prescription volume growth, offset by a decrease of approximately $0.7 million due to lower net pricing resulting from higher co-pay and other patient assistance.

BUPHENYL. Net sales increased $0.4 million, or 10%, to $4.3 million during the three months ended September 30, 2016, from $3.9 million during the three months ended September 30, 2015. Net sales increased by approximately $1.1 million resulting from prescription volume growth, offset by a decrease of approximately $0.7 million due to lower net pricing resulting from higher co-pay and other patient assistance.

LODOTRA. Net sales increased $0.4 million, or 37%, to $1.5 million during the three months ended September 30, 2016, from $1.1 million during the three months ended September 30, 2015. The increase was the result of increased 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.

MIGERGOT. Net sales were $1.2 million during the three months ended September 30, 2016. We began recognizing MIGERGOT sales following the acquisition of Crealta in January 2016.

In September 2016, we entered into a settlement agreement and mutual release with Express Scripts pursuant to which we and Express Scripts were released from any and all claims relating to our then ongoing litigation without admitting any fault or wrongdoing and we agreed to pay Express Scripts $65.0 million. This settlement has been accounted for as a reduction of “net sales” in the condensed consolidated statement of comprehensive loss for the three months ended September 30, 2016.

The table below reconciles our gross to net sales for the three months ended September 30, 2016 and 2015 (in millions):

	Three Months Ended September 30, 2016		Three Months Ended September 30, 2015	
	Amount	% of Gross Sales	Amount	% of Gross Sales
Gross sales	$ 865.9	100.0 %	$ 584.5	100.0 %
Adjustments to gross sales:				
Prompt pay discounts	(16.7)	(1.9)%	(10.5)	(1.8)%
Medicine returns	(9.1)	(1.1)%	(4.2)	(0.7)%
Co-pay and other patient assistance	(458.4)	(52.9)%	(276.1)	(47.2)%
Wholesaler fees and commercial rebates	(30.2)	(3.5)%	(17.4)	(3.0)%
Government rebates and chargebacks	(77.8)	(9.0)%	(49.8)	(8.5)%
Litigation settlement	(65.0)	(7.5)%	—	—
Total adjustments	(657.2)	(75.9)%	(358.0)	(61.2)%
Net sales	$ 208.7	24.1 %	$ 226.5	38.8 %

During the three months ended September 30, 2016, co-pay and other patient assistance, as a percentage of gross sales, increased to 52.9% from 47.2% during the three months ended September 30, 2015. The increase was primarily due to the rollout of our HorizonCares program to all sales territories which helped ensure patient access to our medicines in the face of increased control by certain PBMs and payers.

Cost of Goods Sold. Cost of goods sold increased $23.9 million to $85.2 million during the three months ended September 30, 2016, from $61.3 million during the three months ended September 30, 2015. As a percentage of net sales, cost of goods sold was 40.8% during the three months ended September 30, 2016, compared to 27.0% during the three months ended September 30, 2015. The large increase in costs of goods as a percentage of net sales was due to a decrease in net sales in the three months ended September 30, 2016 as a result of a litigation settlement with Express Scripts. The increase in cost of goods sold was primarily attributable to an increase in intangible amortization expense of $9.1 million, a $4.4 million increase in medicine costs associated with higher sales, a $7.2 million increase in inventory step-up amortization and higher royalty accretion expense of $3.2 million.

The increase in intangible amortization of $9.1 million during the three months ended September 30, 2016 compared to the prior year period was due to the amortization of developed technology related to KRYSTEXXA and MIGERGOT (acquired in January 2016).

The increase in inventory step-up amortization of $7.2 million during the three months ended September 30, 2016 compared to the prior year period was due to $11.3 million recorded during the three months ended September 30, 2016 related to KRYSTEXXA and MIGERGOT inventory step-up (acquired in January 2016) compared to $4.1 million expense recorded during the three months ended September 30, 2015 related to RAVICTI and BUPHENYL inventory step-up (acquired in May 2015).

Research and Development Expenses. Research and development expenses decreased $0.3 million to $12.8 million during the three months ended September 30, 2016, from $13.1 million during the three months ended September 30, 2015. The decrease in research and development expenses during the three months ended September 30, 2016 was

primarily associated with a decrease of $2.2 million in acquisition-related research and development expenses offset by increases in employee and other costs of $1.9 million. During the fourth quarter of 2016, we anticipate investing additional amounts in clinical development, regulatory and commercial functions for a potential launch of ACTIMMUNE for FA. We expect to have top-line results from the STEADFAST study in late December 2016.

Sales and Marketing Expenses. Sales and marketing expenses increased $20.6 million to $72.6 million during three months ended September 30, 2016, from $52.0 million during the three months ended September 30, 2015. The increase in sales and marketing expenses was in line with the significant growth in gross sales and an increase in the number of sales representatives over the same period last year. The increase was primarily attributable to an increase of $11.5 million in employee costs and an increase of $9.6 million in marketing and commercialization expenses, offset by a decrease of $0.5 million in expenses relating to the distribution of medicine samples. As of September 30, 2016, we had approximately 470 sales representatives, a decrease from approximately 500 sales representatives as of June 30, 2016, and this is not expected to be a continuing trend. During the fourth quarter of 2016, we anticipate investing additional amounts in expanding our managed care organization to account for a broader contracting strategy with PBMs and payers, including the addition of national and regional account managers expected to provide long-term durability to our primary care medicines. Additionally, during the fourth quarter of 2016, we anticipate investing in marketing, medical education and commercial infrastructure to support long-term growth of KRYSTEXXA, including new patient access managers to focus on account support of additional KRYSTEXXA treatment sites.

General and Administrative Expenses. General and administrative expenses increased $5.0 million to $59.5 million during the three months ended September 30, 2016, from $54.5 million during the three months ended September 30, 2015. The increase was primarily attributable to an increase of $2.8 million in share-based compensation expenses and $9.4 million related to our growth in headcount and operating costs following the Crealta acquisition, offset by a decrease of $7.2 million in acquisition-related general and administrative expenses.

Interest Expense, Net. Interest expense, net, decreased $1.2 million to $19.1 million during the three months ended September 30, 2016, from $20.3 million during the three months ended September 30, 2015. The decrease was primarily due to a decrease in amortization of debt discount during the three months ended September 30, 2016.

Other Income (Expense) net. Other income (expense), net during the three months ended September 30, 2016 was primarily related to the release of a contingent liability of $6.9 million which was recorded as part of acquisition accounting for Crealta. In December 2015, it was considered probable that the manufacture of the active pharmaceutical ingredient, or API, for KRYSTEXXA would be moved out of Israel based on a notice of termination provided by its contract manufacturer, therefore triggering a repayment obligation to Israel's Office of the Chief Scientist. As a result, Crealta recorded a charge of $6.9 million to cost of goods sold and a corresponding reserve to non-current liabilities. This reserve was then recorded in "Other non-current liabilities" as part of the acquisition accounting for Crealta. Following the execution of an amendment to our agreement with such contract manufacturer and our subsequent determination that the manufacture of the KRYSTEXXA API would not be moved outside of Israel, the contingent liability was released to "Other income (expense)" during the three months ended September 30, 2016.

(Benefit) expense for Income Taxes. During the three months ended September 30, 2016, we recorded a benefit for income taxes of $27.7 million compared to an expense of $22.0 million during the three months ended September 30, 2015. The benefit for income taxes during the three months ended September 30, 2016 was primarily attributable to pre-tax losses incurred in higher tax rate jurisdictions which exceeded pre-tax income in lower tax rate jurisdictions as well as the tax impact of certain discrete factors and events, including the tax benefit recorded as a result of the $65.0 million litigation settlement with Express Scripts.

Comparison of Nine Months Ended September 30, 2016 and 2015

The table below should be referenced in connection with a review of the following discussion of our results of operations for the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015.

	For the Nine Months Ended September 30,		Increase / (Decrease)
	2016	2015	
	(in thousands)		
Net sales	$670,770	$512,506	$158,264
Cost of goods sold	243,520	151,929	91,591
Gross profit	427,250	360,577	66,673
Operating expenses:			
Research and development	36,746	28,176	8,570
Sales and marketing	227,697	157,092	70,605
General and administrative	179,866	157,986	21,880
Total operating expenses	444,309	343,254	101,055

Operating (loss) income	(17,059)	17,323	(34,382)
Other income (expense), net:			
Interest expense, net	(57,752)	(49,780)	7,972
Foreign exchange loss	(266)	(1,010)	(744)
Loss on induced conversion of debt and debt extinguishment	—	(77,624)	(77,624)
Other income (expense), net	6,839	(10,159)	(16,998)
Total other income (expense), net	(51,179)	(138,573)	(87,394)
Loss before benefit for income taxes	(68,238)	(121,250)	(53,012)
Benefit for income taxes	(31,946)	(136,788)	(104,842)
Net (loss) income	$(36,292)	$15,538	$51,830

Net sales. Net sales increased $158.3 million, or 30.9%, to $670.8 million during the nine months ended September 30, 2016, from $512.5 million during the nine months ended September 30, 2015. Excluding the $65.0 million settlement with Express Scripts, as discussed further below, non-GAAP adjusted net sales increased by $223.3 million, or 43.6%, from the same nine month period in the prior year.

The following table presents a summary of total net sales attributed to geographic sources for the nine months ended September 30, 2016 and 2015 (in thousands):

	Nine Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
	Amount	% of Total Net Sales	Amount	% of Total Net Sales
United States	$ 660,608	98 %	$ 505,230	99 %
Rest of world	10,162	2 %	7,276	1 %
Total Net Sales	$ 670,770		$ 512,506	

The following table reflects the components of net sales for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,		Change	Change
	2016	2015	$	%
	(in thousands)			
PENNSAID 2%	$207,857	$91,583	$116,274	127 %
DUEXIS	122,780	129,981	(7,201)	(6 %)
RAVICTI	118,599	52,420	66,179	126 %
VIMOVO	89,710	119,628	(29,918)	(25 %)
ACTIMMUNE	80,465	79,369	1,096	1 %
KRYSTEXXA	61,570	—	61,570	*
RAYOS	36,062	29,191	6,871	24 %
BUPHENYL	12,134	7,822	4,312	55 %
LODOTRA	3,397	2,512	885	35 %
MIGERGOT	3,196	—	3,196	*
Litigation settlement	(65,000)	—	(65,000)	*
Total Net Sales	$670,770	$512,506	$158,264	31 %

*Percentage change is not meaningful.

The increase in net sales during the nine months ended September 30, 2016 was primarily due to the growth in net sales of PENNSAID 2%, the full-period recognition of RAVICTI sales in 2016, compared to a partial period recognition in 2015 following the acquisition of Hyperion in May 2015, and the recognition of KRYSTEXXA sales following the acquisition of Crealta in January 2016, offset by the $65.0 million litigation settlement with Express Scripts along with lower net sales of VIMOVO and DUEXIS.

PENNSAID 2%. Net sales increased $116.3 million, or 127%, to $207.9 million during the nine months ended September 30, 2016, from $91.6 million during the nine months ended September 30, 2015. Net sales increased by approximately $65.8 million resulting from prescription volume growth and approximately $50.5 million due to higher net pricing.

DUEXIS. Net sales decreased $7.2 million, or 6%, to $122.8 million during the nine months ended September 30, 2016, from $130.0 million during the nine months ended September 30, 2015. Net sales decreased by approximately $48.7 million due to lower net pricing resulting from higher co-pay and other patient assistance, offset by an increase of approximately $41.5 million resulting from prescription volume growth.

RAVICTI. Net sales increased $66.2 million, or 126%, to $118.6 million during the nine months ended September 30, 2016, from $52.4 million during the nine months ended September 30, 2015. We began recognizing RAVICTI sales following the closing of the Hyperion acquisition on May 7, 2015, therefore only a partial period of RAVICTI sales were recognized during the nine months ended September 30, 2015, compared with full-period recognition of sales during the nine months ended September 30, 2016.

VIMOVO. Net sales decreased $29.9 million, or 25%, to $89.7 million during the nine months ended September 30, 2016, from $119.6 million during the nine months ended September 30, 2015. Net sales decreased by approximately $35.8 million due to lower net pricing resulting from higher co-pay and other patient assistance, offset by an increase of approximately $5.9 million resulting from prescription volume growth.

ACTIMMUNE. Net sales increased $1.1 million, or 1%, to $80.5 million during the nine months ended September 30, 2016, from $79.4 million during the nine months ended September 30, 2015. Net sales increased by approximately $8.5 million due to higher net pricing, offset by a decrease of approximately $7.4 million resulting from prescription volume decreases.

KRYSTEXXA. Net sales were $61.6 million during the nine months ended September 30, 2016. We began recognizing KRYSTEXXA sales following the acquisition of Crealta in January 2016.

RAYOS. Net sales increased $6.9 million, or 24%, to $36.1 million during the nine months ended September 30, 2016, from $29.2 million during the nine months ended September 30, 2015. Net sales increased by approximately $8.4 million resulting from prescription volume growth, offset by a decrease of approximately $1.5 million due to lower net pricing resulting from higher co-pay and other patient assistance.

BUPHENYL. Net sales increased $4.3 million, or 55%, to $12.1 million during the nine months ended September 30, 2016, from $7.8 million during the nine months ended September 30, 2015. We began recognizing BUPHENYL sales following the closing of the Hyperion acquisition on May 7, 2015, therefore only a partial period of BUPHENYL sales were recognized during the nine months ended September 30, 2015, compared with full-period recognition of sales during the nine months ended September 30, 2016.

LODOTRA. Net sales increased $0.9 million, or 35%, to $3.4 million during the nine months ended September 30, 2016, from $2.5 million during the nine months ended September 30, 2015. The increase was the result of increased medicine shipments to our European distribution partner, 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.

MIGERGOT. Net sales were $3.2 million during the nine months ended September 30, 2016. We began recognizing MIGERGOT sales following the acquisition of Crealta in January 2016.

In September 2016, we entered into a settlement agreement and mutual release with Express Scripts pursuant to which we and Express Scripts were released from any and all claims relating to our then ongoing litigation without admitting any fault or wrongdoing and we agreed to pay Express Scripts $65.0 million. This settlement has been accounted for as a reduction of "net sales" in the condensed consolidated statement of comprehensive loss for the nine months ended September 30, 2016.

The table below reconciles our gross to net sales for the nine months ended September 30, 2016 and 2015 (in millions):

	Nine Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
	Amount	% of Gross Sales	Amount	% of Gross Sales
Gross sales	$2,350.5	100.0 %	$1,378.3	100.0 %
Adjustments to gross sales:				
Prompt pay discounts	(46.8)	(2.0)%	(26.8)	(1.9)%
Medicine returns	(9.3)	(0.4)%	(11.6)	(0.8)%
Co-pay and other patient assistance	(1,275.2)	(54.3)%	(673.5)	(48.9)%
Wholesaler fees and commercial rebates	(85.0)	(3.6)%	(44.3)	(3.2)%
Government rebates and chargebacks	(198.4)	(8.4)%	(109.6)	(8.0)%
Litigation settlement	(65.0)	(2.8)%	—	—
Total adjustments	(1,679.7)	(71.5)%	(865.8)	(62.8)%
Net sales	$670.8	28.5 %	$512.5	37.2 %

During the nine months ended September 30, 2016, co-pay and other patient assistance, as a percentage of gross sales, increased to 54.3% from 48.9% during the nine months ended September 30, 2015. The increase was primarily due to the rollout of our HorizonCares program to all sales territories which helped ensure patient access to our medicines in the face of increased control by certain PBMs and payers. During the nine months ended September 30, 2016, we recorded a net expense reduction of $4.2 million in accrued wholesaler fees and commercial rebates and government rebates and chargebacks resulting from the receipt of lower than estimated invoices related to the year ended December 31, 2015.

Cost of Goods Sold. Cost of goods sold increased $91.6 million to $243.5 million during the nine months ended September 30, 2016, from $151.9 million during the nine months ended September 30, 2015. As a percentage of net sales, cost of goods sold was 36.3% during the nine months ended September 30, 2016 compared to 29.6% during the nine months ended September 30, 2015. The increase in costs of goods as a percentage of net sales was due to a decrease in net sales in the nine months ended September 30, 2016 as a result of a settlement with Express Scripts. The increase in cost of goods sold was primarily attributable to an increase in intangible amortization expense of $60.0 million, a $17.2 million increase in inventory step-up amortization, higher royalty accretion expense of $15.2 million and a $13.5 million increase in medicine costs associated with higher sales, offset by a decrease related to the remeasurement of royalties acquired through business combinations of $14.3 million, recorded during the nine months ended September 30, 2015.

The increase in intangible amortization of $60.0 million during the nine months ended September 30, 2016 compared to the prior year period was due to a $33.9 million increase in amortization expense related to RAVICTI and BUPHENYL intangible assets (acquired in May 2015) and $26.1 million amortization of developed technology related to KRYSTEXXA and MIGERGOT (acquired in January 2016).

The increase in inventory step-up amortization of $17.2 million during the nine months ended September 30, 2016 compared to the prior year period was due to $27.9 million recorded during the nine months ended September 30, 2016 related to KRYSTEXXA and MIGERGOT inventory step-up (acquired in January 2016) compared to $7.5 million recorded during the nine months ended September 30, 2015 related to RAVICTI and BUPHENYL inventory step-up (acquired in May 2015) and $3.2 million related to ACTIMMUNE inventory step-up (acquired in September 2014).

Research and Development Expenses. Research and development expenses increased $8.6 million to $36.8 million during the nine months ended September 30, 2016, from $28.2 million during the nine months ended September 30, 2015. The increase in research and development expenses during the nine months ended September 30, 2016 was primarily associated with an increase of $4.1 million in employee costs, including an increase of $2.1 million in share-based compensation to research and development employees, an increase of $2.8 million in general research and development costs, an increase of $1.4 million in regulatory submission fees and a $2.0 million upfront fee paid for a license of a patent, offset by a decrease of $1.7 million in acquisition-related research and development expenses.

Sales and Marketing Expenses. Sales and marketing expenses increased $70.6 million to $227.7 million during nine months ended September 30, 2016, from $157.1 million during the nine months ended September 30, 2015. The increase in sales and marketing expenses was in line with the significant growth in gross sales and an increase in the number of sales representatives over the same period and was primarily attributable to an increase of $36.1 million in employee costs, including $3.7 million related to share-based compensation resulting from increased staffing of our field sales force, an increase of $31.2 million in marketing and commercialization expenses and an increase of $3.3 million in expenses relating to the distribution of medicine samples.

General and Administrative Expenses. General and administrative expenses increased $21.9 million to $179.9 million during the nine months ended September 30, 2016, from $158.0 million during the nine months ended September 30, 2015. The increase was attributable to $21.3 million of share-based compensation expense, $37.7 million related to our growth in headcount and operating costs following the Hyperion and Crealta acquisitions, offset by a decrease of $37.1 million in acquisition-related general and administrative expenses.

Interest Expense, Net. Interest expense, net, increased $8.0 million to $57.8 million during the nine months ended September 30, 2016, from $49.8 million during the nine months ended September 30, 2015. The increased interest expense, net, was primarily due to full-period recognition during the nine months ended September 30, 2016 of the interest on higher borrowings to fund the acquisition of Hyperion in May 2015, including our $475.0 million aggregate principal amount of 6.625% Senior Notes due 2023, or the 2023 Senior Notes, six-year $400.0 million term loan facility, or the 2015 Term Loan Facility, and $400.0 million aggregate principal amount of 2.50% Exchangeable Senior Notes due 2022, or the Exchangeable Senior Notes, as compared to partial period recognition of the interest on these borrowings during the nine months ended September 30, 2015 and our lower prior year borrowings under our prior five-year $300.0 million term loan facility, or 2014 Term Loan Facility.

Loss on Induced Conversion of Debt and Debt Extinguishment. The loss on induced conversion of debt and debt extinguishment during the nine months ended September 30, 2015 of $77.6 million was composed of $20.7 million related to the induced conversions of our 5.00% Convertible Senior Notes due 2018, or Convertible Senior Notes, and $56.9 million related to the extinguishment of the 2014 Term Loan Facility. The loss on induced conversions consisted of $10.0 million for cash inducement payments, a $10.1 million charge for the extinguishment of debt and $0.6 million of expenses. The loss on extinguishment of the 2014 Term Loan Facility consisted of a $45.4 million early redemption premium and an $11.5 million charge for the extinguishment of debt.

Other Income (Expense) net. Other income (expense), net during the nine months ended September 30, 2016 was primarily related to the release of a contingent liability of $6.9 million which was recorded as part of acquisition

accounting for Crealta. In December 2015, it was considered probable that the manufacture of the API for KRYSTEXXA would be moved out of Israel based on a notice of termination provided by its contract manufacturer, therefore triggering a repayment obligation to Israel's Office of the Chief Scientist. As a result, Crealta recorded a charge of $6.9 million to cost of goods sold and a corresponding reserve to non-current liabilities. This reserve was then recorded in "Other non-current liabilities" as part of the acquisition accounting for Crealta. Following the execution of an amendment to our agreement with such contract manufacturer and our subsequent determination that the manufacture of the KRYSTEXXA API would not be moved outside of Israel, the contingent liability was released to "Other income (expense)" during the nine months ended September 30, 2016. Other income (expense), net during the nine months ended September 30, 2015 totaled $10.2 million, which primarily related to the fees for the Hyperion acquisition financing commitment.

Benefit for Income Taxes. During the nine months ended September 30, 2016, we recorded a benefit for income taxes of $31.9 million compared to $136.8 million during the nine months ended September 30, 2015. The benefit for income taxes during the nine months ended September 30, 2016 was primarily attributable to pre-tax losses incurred in higher tax rate jurisdictions which exceeded pre-tax income in lower tax rate jurisdictions. In addition, during the nine months ended September 30, 2016, we recognized certain discrete items which contributed to the overall tax benefit recognized, including the tax benefit recorded as a result of the $65.0 million litigation settlement with Express Scripts. The benefit for income taxes during the nine months ended September 30, 2015 was primarily attributable to the release of $105.1 million in valuation allowances in the United States due to the recognition of significant deferred tax liabilities as a result of the Hyperion acquisition.

NON-GAAP FINANCIAL MEASURES

EBITDA, or earnings before interest, taxes, depreciation and amortization, and adjusted EBITDA are used and provided by us as non-GAAP financial measures. We provide certain other financial measures such as non-GAAP adjusted net sales, non-GAAP net income and non-GAAP earnings per share which include adjustments to GAAP figures. The exclusion of the $65.0 million litigation settlement from GAAP net sales is the only adjustment reflected in non-GAAP adjusted net sales for the three and nine months ended September 30, 2016. Adjusted EBITDA and non-GAAP net income are intended to provide additional information on our performance, operations and profitability. Adjustments to our GAAP figures as well as EBITDA exclude acquisition-related expenses, an upfront fee for a license of a patent, the Express Scripts litigation settlement amount and loss on debt extinguishment, as well as non-cash items such as share-based compensation, inventory step-up, depreciation and amortization, remeasurement of royalties for medicines acquired through business combinations, royalty accretion, non-cash interest expense, the reversal of a pre-acquisition reserve upon the signing of a contract and other non-cash adjustments. Certain other special items or substantive events may also be included in the non-GAAP adjustments periodically when their magnitude is significant within the periods incurred. We maintain an established non-GAAP cost policy that guides the determination of what costs will be excluded in non-GAAP measures. We believe that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of our financial and operating performance. The non-GAAP financial measures are included with the intent of providing investors with a more complete understanding of our historical and expected 2016 financial results and trends and to facilitate comparisons between periods and with respect to projected information. In addition, these non-GAAP financial measures are among the indicators our management uses for planning and forecasting purposes and measuring our performance. For example, adjusted EBITDA is used by us as one measure of management performance under certain incentive compensation arrangements. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. The non-GAAP financial measures used by us may be calculated differently from, and therefore may not be comparable to, non-GAAP financial measures used by other companies.

Beginning in the second quarter of 2016, we modified the method of calculating non-GAAP income tax expense to align with guidance issued by the SEC on May 17, 2016. The new methodology calculates the income tax component of non-GAAP net income for each period by adjusting the GAAP tax expense (benefit) for the estimated tax impact of each non-GAAP adjustment based on the statutory income tax rate of the applicable jurisdictions for each non-GAAP adjustment. This new methodology does not reflect any use of net operating loss carryforwards that we potentially may have been able to use if our actual earnings for these periods had been the non-GAAP net income. Previously, we had calculated the income tax component of non-GAAP net income by using the estimated cash taxes that we expected to pay for the period. The non-GAAP net income and diluted net income per share amounts shown in the GAAP to non-GAAP reconciliation tables below are based on the new methodology.

Reconciliations of reported GAAP net sales to non-GAAP adjusted net sales, reported GAAP net (loss) income to EBITDA, adjusted EBITDA and non-GAAP net income, and the related per share amounts, are as follows (in

thousands, except share and per share amounts):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
GAAP Net Sales	$ 208,702	$ 226,544	$ 670,770	$ 512,506
Litigation settlement	65,000	—	65,000	—
Non-GAAP Adjusted Net Sales	$ 273,702	$ 226,544	$ 735,770	$ 512,506

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
GAAP Net (Loss) Income	$ (5,870)	$ 3,277	$ (36,292)	$ 15,538
Depreciation	1,183	1,578	3,266	2,808
Amortization and accretion:				
Intangible amortization expense	50,757	41,707	151,199	91,217
Amortization of deferred revenue	(212)	(490)	(631)	(753)
Accretion of royalty liabilities	9,734	6,551	28,762	13,571
Amortization of inventory step-up adjustment	11,305	4,140	27,853	10,635
Interest expense, net (including amortization of debt discount and deferred financing costs)	19,066	20,300	57,752	49,780
(Benefit) expense for income taxes	(27,747)	21,979	(31,946)	(136,788)
EBITDA	58,216	99,042	199,963	46,008
Non-GAAP adjustments:				
Remeasurement of royalties for medicines acquired through business combinations	—	—	—	14,277
Acquisition-related costs	5,159	14,498	16,456	64,841
Upfront fee for license of global patent	—	—	2,000	—
Loss on induced conversion of debt and debt extinguishment	—	—	—	77,624
Share-based compensation	29,312	26,457	84,921	57,796
Royalties for medicines acquired through business combinations (1)	(9,564)	(8,854)	(27,159)	(20,890)
Litigation settlement	65,000	—	65,000	—
Reversal of pre-acquisition reserve upon signing of contract	(6,900)	—	(6,900)	—
Total of non-GAAP adjustments	83,007	32,101	134,318	193,648
Adjusted EBITDA	$ 141,223	$ 131,143	$ 334,281	$ 239,656

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
GAAP Net (Loss) Income	$ (5,870)	$ 3,277	$ (36,292)	$ 15,538
Non-GAAP Adjustments:				
Remeasurement of royalties for medicines acquired through business combinations	—	—	—	14,277
Acquisition-related costs	5,159	14,498	16,456	64,841
Upfront fee for license of global patent	—	—	2,000	—
Loss on induced conversion of debt and debt extinguishment	—	—	—	77,624
Amortization and accretion:				
Intangible amortization expense	50,757	41,707	151,199	91,217
Amortization of debt discount and deferred financing costs	4,537	5,480	13,469	13,328
Accretion of royalty liabilities	9,734	6,551	28,762	13,571
Amortization of inventory step-up adjustment	11,305	4,140	27,853	10,635
Share-based compensation	29,312	26,457	84,921	57,796
Depreciation expense	1,183	1,578	3,266	2,808
Royalties for medicines acquired through business combinations (1)	(9,564)	(8,854)	(27,159)	(20,890)
Litigation settlement	65,000	—	65,000	—
Reversal of pre-acquisition reserve upon signing of contract	(6,900)	—	(6,900)	—
Total pre-tax non-GAAP adjustments	160,523	91,557	358,867	325,207
Income tax effect of pre-tax non-GAAP adjustments (2)	(39,180)	(25,018)	(74,518)	(84,218)
Other non-GAAP income tax adjustments (3)	—	—	—	(105,133)
Total non-GAAP adjustments	121,343	66,539	284,349	135,856
Non-GAAP Net Income	$ 115,473	$ 69,816	$ 248,057	$ 151,394
Non-GAAP Earnings Per Share:				
Weighted average ordinary shares – Basic	161,038,827	159,035,580	160,472,530	145,208,252

Non-GAAP Earnings Per Share – Basic				
GAAP (loss) earnings per share – Basic	$ (0.04)	$ 0.02	$ (0.23)	$ 0.11
Non-GAAP adjustments	0.76	0.42	1.78	0.93
Non-GAAP earnings per share – Basic	$ 0.72	$ 0.44	$ 1.55	$ 1.04
Weighted average ordinary shares – Diluted				
Weighted average ordinary shares – Basic	161,038,827	159,035,580	160,472,530	145,208,252
Ordinary share equivalents	3,868,212	7,795,220	3,763,984	8,797,419
Weighted average ordinary shares – Diluted	164,907,039	166,830,800	164,236,514	154,005,671
Non-GAAP Earnings Per Share – Diluted				
GAAP (loss) earnings per share – Diluted	$ (0.04)	$ 0.02	$ (0.23)	$ 0.10
Non-GAAP adjustments	0.75	0.40	1.77	0.88
Diluted earnings per share effect of ordinary share equivalents	(0.01)	—	(0.03)	—
Non-GAAP earnings per share – Diluted	$ 0.70	$ 0.42	$ 1.51	$ 0.98

(1) Royalties for medicines acquired through business combinations relate to ACTIMMUNE, BUPHENYL, KRYSTEXXA, MIGERGOT, RAVICTI and VIMOVO.

(2) Adjustment to the GAAP tax (benefit) expense for the estimated tax impact of each non-GAAP adjustment based on the statutory tax rate of the applicable jurisdictions for each non-GAAP adjustment.

(3) Other non-GAAP income tax adjustments in the nine months ended September 30, 2015 of $105.1 million related to the release of certain valuation allowances in connection with the Hyperion acquisition.

LIQUIDITY, FINANCIAL POSITION AND CAPITAL RESOURCES

We have incurred losses since our inception in June 2005 and, as of September 30, 2016, we had an accumulated deficit of $717.5 million. We expect that our sales and marketing expenses will continue to increase as a result of our commercialization of our medicines, but we believe these cost increases will be more than offset by higher net sales and gross profits. We achieved operating profitability in the year ended December 31, 2015. While we have incurred operating losses of $21.3 million and $17.1 million for the three and nine months ended September 30, 2016, respectively, excluding the non-recurring $65.0 million litigation settlement with Express Scripts during the three months ended September 30, 2016, we achieved operating profitability during such periods and we expect our current operations to continue to achieve operating profitability in 2016, absent unusual or non-recurring items.

Our cash position as of September 30, 2016 does not reflect our use of approximately $207.6 million of cash on hand to fund our acquisition of Raptor on October 25, 2016.

We have financed our operations to date through equity financings, debt financings and the issuance of convertible notes, along with cash flows from operations during the last several quarters. As of September 30, 2016, we had $549.3 million in cash and cash equivalents and total debt with a book value of $1,147.2 million and face value of $1,270.0 million. We believe our existing cash and cash equivalents and our expected cash flows from our operations will be sufficient to fund our business needs for at least the next 12 months. Part of our strategy is to expand and leverage our commercial capabilities by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs. To the extent we enter into transactions to acquire medicines or businesses in the future, we will most likely need to finance a significant portion of those acquisitions through additional debt, equity or convertible debt financings.

In March 2015, April 2015 and June 2015, we entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes which were on substantially the same terms as prior conversion agreements entered into by us. Under these conversion agreements, the applicable holders agreed to convert an aggregate principal amount of $61.0 million of Convertible Senior Notes held by them and we agreed to settle such conversions by issuing an aggregate of 11,368,921 ordinary shares. In addition, pursuant to such conversion agreements, we made an aggregate cash payment of $10.0 million to the applicable holders for additional exchange consideration and $0.9 million for accrued and unpaid interest. Following these conversions, there were no Convertible Senior Notes remaining outstanding.

On March 13, 2015, Horizon Pharma Investment Limited, a wholly owned subsidiary of Horizon Pharma plc, or Horizon Investment, completed a private placement of $400.0 million aggregate principal amount of Exchangeable Senior Notes to several 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.

We have fully and unconditionally guaranteed the Exchangeable Senior Notes on a senior unsecured basis, or the Guarantee. The Exchangeable Senior Notes and the Guarantee are Horizon Investment's and our 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 of our ordinary shares per $1,000 principal amount of the Exchangeable Senior Notes (equivalent to an initial exchange price of approximately $28.66 per ordinary share).

On April 21, 2015, we closed an underwritten public offering of 17,652,500 of our ordinary shares at a price to the public of $28.25 per share, or the 2015 Offering. The net proceeds to us from the 2015 Offering were approximately $475.6 million, after deducting underwriting discounts and other offering expenses payable by us.

On April 29, 2015, Horizon Pharma Financing Inc., our then wholly owned subsidiary, or Horizon Financing, completed a private placement of $475.0 million aggregate principal amount of 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 and in offshore transactions to non-U.S. Persons in reliance on Regulation S under the Securities Act. The net proceeds from the 2023 Senior Notes were approximately $462.3 million.

In connection with the closing of the Hyperion acquisition 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 and we and all of our direct and indirect subsidiaries that are guarantors under the 2015 Senior Secured Credit Facility (as described below) fully and unconditionally guaranteed on a senior unsecured basis HPI’s obligations under the 2023 Senior Notes.

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 exchanged, repurchased or redeemed.

Except as described below, the 2023 Senior Notes may not be redeemed before May 1, 2018. Thereafter, 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. At any time prior to May 1, 2018, some or all of the 2023 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, but not including, the redemption date. Also prior to May 1, 2018, up to 35% of the aggregate principal amount of the 2023 Senior Notes may be redeemed at a redemption price of 106.625% of the aggregate principal amount thereof, plus accrued and unpaid interest, with the net proceeds of certain equity offerings; provided that: (1) at least 65% of the aggregate principal amount of notes originally issued under the indenture (excluding notes held by the parent and its subsidiaries) remains outstanding immediately after the occurrence of such redemption; and (2) the redemption occurs with 180 days of the date of closing such equity offering. 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 we undergo 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 we or certain of our subsidiaries engage 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.

On May 7, 2015, we, HPI, and certain of our subsidiaries entered into a credit agreement with Citibank N.A., as administrative agent and collateral agent, and the lenders from time to time party thereto, or, as amended, the credit agreement, providing for (i) the six-year $400.0 million 2015 Term Loan Facility; (ii) an uncommitted accordion facility subject to the satisfaction of certain financial and other conditions; and (iii) one or more uncommitted refinancing loan facilities with respect to loans thereunder, or the 2015 Senior Secured Credit Facility. The initial borrower under the 2015 Term Loan Facility is HPI. The credit agreement allows for us and certain of our other subsidiaries to become borrowers under the accordion or refinancing facilities. Until October 25, 2016, loans under the 2015 Term Loan Facility bore interest, at each borrower's option, at a rate equal to either the London Inter-Bank Offer Rate, or LIBOR, plus an applicable margin of 3.50% per year (subject to a 1.0% LIBOR floor), or the adjusted base rate plus 2.50%. The issuance of the Incremental Loans (as defined below) resulted in an increase of the interest rate applicable to the loans under the 2015 Term Loan Facility, as of October 25, 2016, to LIBOR plus an applicable margin of 4.00% per year (subject to a 1.0% LIBOR floor), or the adjusted base rate plus 3.00%. The adjusted base rate is defined as the greater of (a) LIBOR (using one-month interest period) plus 1%, (b) prime rate, (c) fed funds plus ½ of 1% and (d) 2%. We borrowed the full $400.0 million available under the 2015 Term Loan Facility on May 7, 2015 as a LIBOR-based borrowing. The net proceeds from the 2015 Term Loan Facility were approximately $391.7 million.

The obligations under the credit agreement and any swap obligations and cash management obligations owing to a lender (or an affiliate of a lender) thereunder are and will be guaranteed by our and each of our existing and subsequently acquired or organized 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 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).

We are permitted to make voluntary prepayments at any time without payment of a premium. We are required to make mandatory prepayments of loans under the 2015 Term Loan Facility (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) beginning with the fiscal year ending December 31, 2016, 50% of our excess cash flow (subject to decrease to 25% or 0% if our first lien leverage ratio is less than 2.25:1 and 1.75:1, respectively). The loans under the 2015 Term Loan Facility will amortize in equal quarterly installments in an aggregate annual amount equal to 1% of the original principal amount thereof, with any remaining balance payable on the final maturity date of the loans under the 2015 Term Loan Facility.

We used the net proceeds from the 2015 Offering, the offering of the 2023 Senior Notes, borrowings under the 2015 Term Loan Facility and existing cash to fund our acquisition of Hyperion, repay the $300.0 million outstanding amounts under the 2014 Term Loan Facility plus the related $45.4 million make-whole fee, and pay prepayment premiums, fees and expenses in connection with the foregoing.

On October 25, 2016, HPI and Horizon Pharma USA, Inc., our wholly-owned subsidiary, or HPUSA, and, together with HPI, the 2024 Issuers, completed a private placement of $300.0 million aggregate principal amount of 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 2024 Senior Notes are the 2024 Issuers' general unsecured senior obligations and we and all of our direct and indirect subsidiaries that are guarantors under the 2015 Senior Secured Credit Facility and the 2016 Incremental Loan Facility (as defined below) fully and unconditionally guaranteed on a senior unsecured basis the 2024 Issuers' obligations under the 2024 Senior Notes.

The 2024 Senior Notes accrue interest at an annual rate of 8.75% 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 exchanged, 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 we undergo 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 we or certain of our subsidiaries engage 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.

On October 25, 2016, HPI and HPUSA, together, in such capacity, the Incremental Borrowers, entered into an amendment to the credit agreement, or the 2016 Amendment, with Citibank, N.A., as administrative and collateral agent, and Bank of America, N.A., as the incremental B-1 lender thereunder, pursuant to which the Incremental Borrowers borrowed $375.0 million aggregate principal amount of loans, or the 2016 Incremental Loan Facility. The 2016 Incremental Loan Facility was incurred as a separate class of term loans under the credit agreement with the same terms of loans under the 2015 Term Loan Facility, except as described below.

Loans under the 2016 Incremental Loan Facility bear interest, at each Incremental Borrowers' option, at a rate equal to either LIBOR plus an applicable margin of 4.50% per year (subject to a LIBOR floor of 1.0%), or the adjusted base rate plus 3.50%. The terms of the loans under the 2015 Term Loan Facility, or the 2015 Loans, provided for an amendment such that the effective yield of the 2015 Loans would not be less than the effective yield of the loans under the 2016 Incremental Loan Facility, or the Incremental Loans, minus 0.50%. Consequently, the issuance of the Incremental Loans resulted in an increase of the interest rate applicable to the 2015 Loans, as of October 25, 2016, to LIBOR plus 4.00%, subject to a LIBOR floor of 1.0% (an initial interest rate of 5.00%). 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, except that with respect to the Incremental Loans, a 1% premium will apply to a repayment of the Incremental Loans in connection with a re-pricing of, or any amendment to the credit agreement in a re-pricing of, such loans effected on or prior to the date that is twelve months following October 25, 2016.

We used the net proceeds of the offering of the 2024 Senior Notes, borrowings under the 2016 Incremental Facility and existing cash to fund our acquisition of Raptor, plus the related fees and expenses in connection with the foregoing.

We have a significant amount of debt outstanding on a consolidated basis. This substantial level of debt could have important consequences to our business, including, but not limited to: making it more difficult for us to satisfy our obligations; requiring a substantial portion of our cash flows from operations to be dedicated to the payment of principal and interest on our indebtedness, therefore reducing our ability to use our cash flows to fund acquisitions, capital expenditures, and future business opportunities; limiting our ability to obtain additional financing, including borrowing additional funds; increasing our vulnerability to, and reducing our flexibility to respond to, general adverse economic and industry conditions; limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; and placing us at a disadvantage as compared to our competitors, to the extent that they are not as highly leveraged. We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness.

In addition, the indentures governing the 2024 Senior Notes and 2023 Senior Notes and the credit agreement related to the 2015 Senior Secured Credit Facility and 2016 Incremental Facility impose various covenants that limit our ability and/or our restricted subsidiaries' ability 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 or merger transactions, 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 us.

During the nine months ended September 30, 2016, we issued an aggregate of:

- 496,012 ordinary shares in connection with the exercise of stock options and received $3.4 million in proceeds;
- 619,696 ordinary shares in net settlement of vested restricted stock units;
- 13,584 ordinary shares in net settlement of vested performance stock units; and
- 261,780 ordinary shares pursuant to employee stock purchase plans and received $3.2 million in proceeds.

During the nine months ended September 30, 2016, warrants to purchase an aggregate of 207,110 of our ordinary shares were exercised in cashless exercises, resulting in the issuance of 161,259 ordinary shares. As of September 30, 2016, there were outstanding warrants to purchase 1,374,410 of our ordinary shares.

During the nine months ended September 30, 2016, we made payments of $5.3 million for employee withholding taxes relating to share-based awards.

In May 2016, our board of directors authorized a share repurchase program pursuant to which we may repurchase up to 5,000,000 of our ordinary shares. The timing and amount of repurchases, including whether we decide to repurchase any shares pursuant to the authorization, will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, our cash resources, restrictions under our credit agreement, and market conditions. As of September 30, 2016, we had not purchased any of our ordinary shares under this repurchase program.

Sources and Uses of Cash

The following table provides a summary of our cash position and cash flows as of and for the nine months ended September 30, 2016 and 2015 (in thousands):

	2016	2015
Cash and cash equivalents	$549,303	$684,286
Cash provided by (used in):		
Operating activities	230,271	59,228
Investing activities	(538,432)	(1,034,187)
Financing activities	(1,690)	1,440,587

Operating Cash Flows

During the nine months ended September 30, 2016, net cash provided by operating activities was $230.3 million compared to $59.2 million during the nine months ended September 30, 2015. The increase in net cash provided by operating activities was primarily attributable to higher cash collections from accounts receivable balances as a result of an increase in sales of medicines, partially offset by higher cash outlays for contractual allowances, patient access

programs and government rebates and chargebacks. The payment of the $65.0 million litigation settlement with Express Scripts was not made during the nine months ended September 30, 2016 and therefore had no impact on operating cash flows. This settlement amount will be paid to Express Scripts in installments, with 50 percent of the installment due in the fourth quarter of 2016, 25 percent in the first quarter of 2017 and 25 percent in the second quarter of 2017.

Cash provided by operating activities was negatively impacted during the nine months ended September 30, 2016 due to cash payments of $39.5 million for interest payments made on our 2015 Term Loan Facility, 2023 Senior Notes and Exchangeable Senior Notes, $27.5 million for costs related to acquisitions, $18.5 million of cash paid for income taxes and $2.0 million of cash paid for an upfront fee for a license of a global patent. During the nine months ended September 30, 2015, we made cash payments of $55.4 million for induced conversions and debt extinguishment and related expenses, $49.2 million for costs related to acquisitions, $21.4 million for interest payments, $11.2 million for employee and director-related excise taxes due to the Vidara Merger, $9.0 million for fees relating to a debt commitment and $1.9 million for income taxes.

Investing Cash Flows

During the nine months ended September 30, 2016 and 2015, net cash used in investing activities was $538.4 million and $1,034.2 million, respectively. The net cash used in investing activities during the nine months ended September 30, 2016 was primarily associated with $514.8 million of payments for the acquisition of Crealta, net of cash acquired, a $5.6 million (€5.0 million) initial payment for certain intellectual property rights to interferon gamma-1b for the treatment of FA and $14.6 million of payments for purchases of property and equipment. The net cash used in investing activities during the nine months ended September 30, 2015 was primarily associated with payments for the acquisition of Hyperion in May 2015 of $1,022.4 million, net of cash acquired, and payments of $71.8 million for purchases of long-term investments, offset by $64.6 million in proceeds from the liquidation of available-for-sale investments.

Financing Cash Flows

During the nine months ended September 30, 2016, net cash used in financing activities was $1.7 million compared to net cash provided by financing activities of $1,440.6 million during the nine months ended September 30, 2015. The decrease in net cash provided by financing activities during the nine months ended September 30, 2016 was primarily attributable to the absence of any new financings being completed during the nine months ended September 30, 2016, as the financings to fund the acquisition of Raptor did not close until October 25, 2016. Net cash provided by financing activities during the nine months ended September 30, 2015 was primarily attributable to $475.6 million of net proceeds from the 2015 Offering, $462.3 million of net proceeds from the issuance of the 2023 Senior Notes, $391.5 million of net proceeds from the 2015 Term Loan Facility, $387.2 million of net proceeds received from borrowings under the Exchangeable Senior Notes, and was negatively impacted by the repayment of $297.0 million and $1.0 million of the 2014 Term Loan Facility and 2015 Term Loan Facility, respectively.

Financial Condition as of September 30, 2016 compared to December 31, 2015

Accounts receivable, net. Accounts receivable, net, increased $152.5 million, from $210.4 million as of December 31, 2015 to $362.9 million as of September 30, 2016. The increase is due to growth in gross sales of our medicines, from December 2015 to September 2016.

Inventories, net. Inventories, net, increased $143.8 million, from $18.4 million as of December 31, 2015 to $162.2 million as of September 30, 2016. This increase is primarily due to $134.0 million of stepped-up KRYSTEXXA and MIGERGOT inventory at September 30, 2016 recorded as a result of the Crealta acquisition in January 2016.

Prepaid expenses and other current assets. Prepaid expenses and other current assets increased $22.2 million, from $15.9 million as of December 31, 2015 to $38.1 million as of September 30, 2016. The increase is primarily due to $13.4 million of quarterly estimated income tax installments paid as of September 30, 2016, an increase of $4.0 million in medicine samples inventory and an additional $2.0 million of rabbi trust assets held at September 30, 2016.

Developed technology, net. Developed technology, net, increased $268.1 million, from $1,609.1 million as of December 31, 2015 to $1,877.2 million as of September 30, 2016. The increase is due to $418.7 million of KRYSTEXXA and MIGERGOT developed technology acquired in the Crealta acquisition, offset by amortization of developed technology on our medicines acquired through acquisitions of $150.6 million during the nine months ended September 30, 2016.

Other assets. Other assets increased $6.0 million, from $0.2 million as of December 31, 2015 to $6.2 million as of September 30, 2016. This increase is primarily due to an upfront payment of $5.6 million (€5.0 million) to Boehringer Ingelheim International upon the signing of a definitive agreement to acquire worldwide rights to interferon

gamma-1b.

Accounts payable. Accounts payable increased $49.1 million, from $16.6 million as of December 31, 2015 to $65.7 million as of September 30, 2016. This increase is primarily due to $42.5 million of trade discounts and rebates included within accounts payable as of September 30, 2016 and timing of payments.

Accrued expenses. Accrued expenses increased $57.5 million, from $100.0 million as of December 31, 2015 to $157.5 million as of September 30, 2016. This is due to an accrued litigation settlement amount of $65.0 million as of September 30, 2016, following the litigation settlement with Express Scripts, an increase of $8.5 million in consulting and professional services fee accruals, an increase of $5.6 million in accrued interest, offset by decreases in payroll-related accrued expenses of $12.2 million and other accrued expenses of $9.4 million.

Accrued trade discounts and rebates. Accrued trade discounts and rebates increased $84.4 million, from $183.8 million as of December 31, 2015 to $268.2 million as of September 30, 2016. This is due to a $59.0 million increase in accrued co-pay and other patient assistance, a $18.5 million increase in accrued government rebates and chargebacks and a $6.9 million increase in accrued wholesaler fees and commercial rebates. These increases are in line with the increase in gross sales during the period.

Accrued royalties, net of current. Accrued royalties, net of current, increased $46.1 million, from $123.5 million as of December 31, 2015 to $169.6 million as of September 30, 2016. This increase is primarily due to KRYSTEXXA and MIGERGOT contingent royalties of $47.9 million at September 30, 2016 as a result of the Crealta acquisition in January 2016.

Deferred tax liabilities, net. Deferred tax liabilities, net, decreased $17.8 million, from $113.4 million as of December 31, 2015 to $95.6 million as of September 30, 2016. The decrease was as a result of the tax benefit recorded in the condensed consolidated statement of comprehensive loss during the nine months ended September 30, 2016 and the correction of an error in the Hyperion pre-acquisition deferred tax calculation, as described in Note 3 “Business Acquisitions” in the notes to our condensed consolidated financial statements included in this report, offset by the recording of deferred tax liabilities in connection with the acquisition of Crealta in January 2016.

Other long-term liabilities. Other long-term liabilities increased $5.5 million, from $9.4 million as of December 31, 2015 to $14.9 million as of September 30, 2016. The increase is primarily due to an increase of $2.0 million in long-term deferred compensation plan liabilities and $1.7 million of increased tax liabilities.

Contractual Obligations

During the nine months ended September 30, 2016, there were no material changes outside of the ordinary course of business to our contractual obligations as previously disclosed in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, except for the changes described below.

On October 25, 2016, we completed a private placement of $300.0 million aggregate principal amount of the 2024 Senior Notes. The 2024 Senior Notes will accrue interest at an annual rate of 8.75% 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 exchanged, repurchased or redeemed.

On October 25, 2016, we entered into the 2016 Incremental Facility and the Incremental Borrowers borrowed the entire $375.0 million available under the 2016 Incremental Facility. Loans under the 2016 Incremental Loan Facility bear interest, at each Incremental Borrowers’ option, at a rate equal to either LIBOR plus an applicable margin of 4.50% per year (subject to a LIBOR floor of 1.0%), or the adjusted base rate plus 3.50%. The terms of the 2015 Term Loan Facility provided for an amendment such that the effective yield of the 2015 Term Loan Facility would not be less than the effective yield of the 2016 Incremental Loans minus 0.50%. Consequently, the issuance of the 2016 Incremental Loans resulted in an increase of the interest rate applicable to the 2015 Term Loan Facility, as of October 25, 2016, to LIBOR plus 4.00%, subject to a LIBOR floor of 1.0% (an initial interest rate of 5.00%). Thus, loans under the 2015 Term Loan Facility bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.00% per annum (subject to a 1.00% LIBOR floor), or the adjusted base rate plus 3.00%. The adjusted base rate is defined as the greater of (a) LIBOR (using one-month interest period) plus 1%, (b) prime rate, (c) fed funds plus ½ of 1% and (d) 2%.

In October 2016, we committed to purchase additional units of ACTIMMUNE from Boehringer Ingelheim in 2017 at a cost of $7.3 million. These additional units of ACTIMMUNE are intended to cover anticipated demand if the results of the STEADFAST study of ACTIMMUNE for the treatment of FA are successful and we subsequently receive U.S. marketing approval for FA. Top-line results from the study are expected in late December 2016, and if the trial is not successful, we may have excess ACTIMMUNE inventory and/or purchase commitments.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements in accordance with U.S. GAAP principles requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenue and expenses. Certain of these policies are considered critical as these most significantly impact a company's financial condition and results of operations and require the most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Actual results may vary from these estimates. A summary of our significant accounting policies is included in Note 2 to our Annual Report on Form 10-K for the year ended December 31, 2015. There have been no significant changes in our application of our critical accounting policies during the nine months ended September 30, 2016.

OFF-BALANCE SHEET ARRANGEMENTS

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities, other than the indemnification agreements discussed in Note 12, "Commitments and Contingencies" in the notes to our condensed consolidated financial statements included in this report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various market risks, which include potential losses arising from adverse changes in market rates and prices, such as interest rates and foreign exchange fluctuations. We do not enter into derivatives or other financial instruments for trading or speculative purposes.

Interest Rate Risk. We are subject to interest rate fluctuation exposure through our borrowings under the 2015 Term Loan Facility and our investment in money market accounts which bear a variable interest rate. The terms of the 2015 Term Loan Facility provided for an amendment such that the effective yield of the 2015 Term Loan Facility would not be less than the effective yield of the 2016 Incremental Loans minus 0.50%. Consequently, the issuance of the 2016 Incremental Loans resulted in an increase of the interest rate applicable to the 2015 Term Loan Facility, as of October 25, 2016, to LIBOR plus 4.00%, subject to a LIBOR floor of 1.0% (an initial interest rate of 5.00%). Thus, loans under the 2015 Term Loan Facility bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.00% per annum (subject to a 1.00% LIBOR floor), or the adjusted base rate plus 3.00%. The adjusted base rate is defined as the greater of (a) LIBOR (using one-month interest period) plus 1%, (b) prime rate, (c) fed funds plus ½ of 1% and (d) 2%. Since drawing the full $400.0 million available in May 2015, our borrowings had been based on LIBOR. Since current LIBOR rates are below the 1.0% LIBOR floor, the interest rate on our borrowings has been 5.00% per annum.

An increase in the LIBOR of 100 basis points above the 1.0% LIBOR floor would increase our interest expense related to the 2015 Term Loan Facility by $4.0 million per year.

The goals of our investment policy are associated with the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market risk, we maintain our excess cash and cash equivalents in money market funds. Because of the short-term maturities of our cash equivalents, we do not believe that a decrease in interest rates would have any material negative impact on the fair value of our cash equivalents.

Foreign Currency Risk. Our purchase cost of ACTIMMUNE under our contract with Boehringer Ingelheim RCV GmbH & Co. KG as well as our sales contracts relating to LODOTRA are principally denominated in Euros and are subject to foreign currency risk. We also incur certain operating expenses in currencies other than the U.S. dollar in relation to our Irish operations and foreign subsidiaries, including Horizon Pharma Switzerland GmbH; therefore, we are subject to volatility in cash flows due to fluctuations in foreign currency exchange rates, particularly changes in the Euro. Following the acquisition of Raptor, we are subject to increased foreign currency risk for our operations in Europe due to an increased level of sales and operating expenses denominated in Euros. To date, we have not entered into any hedging contracts since exchange rate fluctuations have had minimal impact on our results of operations and cash flows.

Inflation Risk. We do not believe that inflation has had a material impact on our business or results of operations during the periods for which the condensed consolidated financial statements are presented in this report.

Credit Risk. Historically, our accounts receivable balances have been highly concentrated with a select number of customers consisting primarily of large wholesale pharmaceutical distributors who, in turn, sell the medicines to pharmacies, hospitals and other customers. For the nine months ended September 30, 2016, our top five customers, AmerisourceBergen, Cardinal Health, Inc., CVS Health, McKesson Corporation and Rochester Drug Company accounted for approximately 85% of total consolidated gross sales. For the nine months ended September 30, 2015, our top five customers, American Specialty Pharmacy, Inc., AmerisourceBergen, Cardinal Health, Inc., McKesson Corporation and Rochester Drug Company accounted for approximately 82% of total consolidated gross sales.

In addition, five customers, AmerisourceBergen, Cardinal Health, Inc., CVS Health, McKesson Corporation and Rochester Drug Company accounted for approximately 95% of our total outstanding accounts receivable balances at September 30, 2016. Five customers, American Specialty Pharmacy, Inc., AmerisourceBergen, Cardinal Health, Inc., McKesson Corporation and Rochester Drug also accounted for approximately 90% of our total outstanding accounts receivable balances at September 30, 2015. Historically, we have not experienced any significant losses related to our accounts receivable balances.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. As required by paragraph (b) of Rules 13a-15 and 15d-15 promulgated under the Exchange Act, our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report of the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2016, the end of the period covered by this report.

Changes in Internal Control Over Financial Reporting. We are in the process of implementing new enterprise resource planning software, SAP, as part of a plan to integrate and upgrade our systems and processes. The implementation of this global software is scheduled to continue in phases over a number of years. During the first nine months of 2016, we migrated certain areas of our business to SAP, including financial reporting, financial planning and analysis, supply chain and treasury. As the phased implementation of this system occurs, we are experiencing certain changes to our processes and procedures which, in turn, result in changes to our internal control over financial reporting. While we expect SAP to strengthen our internal financial controls by automating certain manual processes and standardizing business processes and reporting across our organization, management will continue to evaluate and monitor our internal controls as processes and procedures in each of the affected areas evolve.

During the three months ended September 30, 2016, other than continuing changes to our internal control processes resulting from new enterprise resource planning software, as discussed above, there have been no material changes to our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f), that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For a description of our legal proceedings, see Note 13, Legal Proceedings, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q.

ITEM 1A: RISK FACTORS

You should consider carefully the risks described below, together with all of the other information included in this report, and in our other filings with the Securities and Exchange Commission, or SEC, before deciding whether to invest in or continue to hold our ordinary shares. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our ordinary shares to decline, resulting in a loss of all or part of your investment.

The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing changes, including any material changes, from the risk factors previously disclosed in Item 1A of our annual report on Form 10-K for the year ended December 31, 2015, as filed with the SEC.

Risks Related to Our Business and Industry

Our ability to generate revenues from our medicines is subject to attaining significant market acceptance among physicians, patients and healthcare payers.*

Our current medicines, and other medicines or medicine candidates that we may develop or acquire, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. We have a limited history of commercializing medicines and most of our medicines have not been on the market for an extensive period of time, which subjects us to numerous risks as we attempt to increase our market share. We believe that the degree of market acceptance and our ability to generate revenues from our medicines will depend on a number of factors, including:

- timing of market introduction of our medicines as well as competitive medicines;
- efficacy and safety of our medicines;
- continued projected growth of the markets in which our medicines compete;
- prevalence and severity of any side effects;
- if and when we are able to obtain regulatory approvals for additional indications for our medicines;
- acceptance by patients, primary care physicians and key specialists, including rheumatologists, orthopedic surgeons, pain specialists, podiatrists, medical geneticists and specialists in pediatric immunology, allergy, infectious diseases and hematology/oncology;
- availability of coverage and adequate reimbursement and pricing from government and other third-party payers;

- potential or perceived advantages or disadvantages of our medicines over alternative treatments, including cost of treatment and relative convenience and ease of administration;
- strength of sales, marketing and distribution support;
- the price of our medicines, both in absolute terms and relative to alternative treatments;
- impact of past and limitation of future medicine price increases;
- our ability to maintain a continuous supply of medicine for commercial sale;
- the effect of current and future healthcare laws;
- the performance of third-party distribution partners, over which we have limited control; and
- medicine labeling or medicine insert requirements of the U.S. Food and Drug Administration, or FDA, or other regulatory authorities.

With respect to DUEXIS and VIMOVO, studies indicate that physicians do not commonly co-prescribe gastrointestinal, or GI, protective agents to high-risk patients taking nonsteroidal anti-inflammatory drugs, or NSAIDs. We believe this is due in part to a lack of awareness among physicians prescribing NSAIDs regarding the risk of NSAID-induced upper GI ulcers, in addition to the inconvenience of prescribing two separate medications and patient compliance issues associated with multiple prescriptions. If physicians remain unaware of, or do not otherwise believe in, the benefits of combining GI protective agents with NSAIDs, our market opportunity for DUEXIS and VIMOVO will be limited. Some physicians may also be reluctant to prescribe DUEXIS or VIMOVO due to the inability to vary the dose of ibuprofen and naproxen, respectively, or if they believe treatment with NSAIDs or GI protective agents other than those contained in DUEXIS and VIMOVO, including those of its competitors, would be more effective for their patients. With respect to each of DUEXIS, PENNSAID 2% w/w, or PENNSAID 2%, RAYOS/LODOTRA, VIMOVO and BUPHENYL, their higher cost compared to the generic or branded forms of their active ingredients alone may limit adoption by physicians, patients and healthcare payers. With respect to ACTIMMUNE, while it is the only FDA-approved treatment for chronic granulomatous disease, or CGD, and severe, malignant osteopetrosis, or SMO, they are very rare conditions and, as a result, our ability to grow ACTIMMUNE sales will depend on our ability to further penetrate this limited market and obtain marketing approval for additional indications. With respect to RAVICTI, which is also approved to treat a very limited patient population, our ability to grow sales will depend in large part on our ability to transition urea cycle disorder, or UCD, patients from BUPHENYL or generic equivalents, which are comparatively much less expensive, to RAVICTI. With respect to KRYSTEXXA, our ability to grow sales will be affected by the success of our sales and marketing strategies and life cycle management, including studies designed to test reduction of immunogenicity in KRYSTEXXA which could expand the patient population and usage of KRYSTEXXA. With respect to MIGERGOT, our ability to sustain sales will depend on the management of inventory levels and the continued awareness of its benefits among physicians. With respect to PROCYSBI, which is approved to treat a very limited patient population, our ability to grow sales will depend in large part on our ability to transition patients from the first-generation therapy to PROCYSBI, to identify additional patients with nephropathic cystinosis, and expand commercialization in Europe. Unless QUINSAIR is approved for marketing in additional countries, our ability to drive growth of this medicine will largely depend on expanding its use in Europe and Canada. If our current medicines or any other medicine that we may seek approval for or acquire fail to attain market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects (including, possibly, the value of our ordinary shares).

Our future prospects are highly dependent on our ability to successfully formulate and execute commercialization strategies for each of our medicines. Failure to do so would adversely impact our financial condition and prospects.*

A substantial majority of our resources are focused on the commercialization of our current medicines. Our ability to generate significant medicine revenues and to achieve commercial success in the near-term will initially depend almost entirely on our ability to successfully commercialize these medicines in the United States.

With respect to our orphan medicines, ACTIMMUNE, BUPHENYL, PROCYSBI, QUINSAIR and RAVICTI, and with respect to our rheumatology medicine KRYSTEXXA, our commercialization strategy includes efforts to increase awareness of the rare conditions that each medicine is designed to treat, enhancing efforts to identify target patients and in certain cases pursue opportunities for label expansion and more effective use through clinical trials. In addition, our strategy with respect to ACTIMMUNE includes pursuing label expansion for additional indications, such as Friedreich’s ataxia, or FA, and price increases but we cannot be certain that our pricing strategy will not result in downward pressure on sales or that we will be able to successfully complete clinical trials and obtain regulatory approvals in additional indications. With respect to RAVICTI and PROCYSBI, our strategy includes accelerating the transition of patients from first-generation therapies, and increasing the diagnosis of the associated rare conditions through patient and physician outreach. Part of our success in our strategy for RAVICTI will also depend on obtaining approval of RAVICTI for the treatment of UCD in patients less than two years of age. On June 29, 2016, we

submitted a supplemental new drug application, or sNDA, with the FDA for RAVICTI to expand the age range for chronic management of UCDs from two years of age and older to two months of age and older. Subject to positive data from on-going studies, we have targeted an sNDA submission in the first quarter of 2018 in relation to UCD patients during the first two months of life, however, we cannot guarantee that on-going studies will be positive or that we will be able to expand the labeling for RAVICTI on our anticipated timeline or at all. Our strategy with respect to KRYSTEXXA includes the expansion of our sales force, the planned enhancement of the KRYSTEXXA marketing campaign with improved immunogenicity data, continued volume growth and pricing optimization.

With respect to our primary care medicines DUEXIS, PENNSAID 2% and VIMOVO, our strategy has included bringing pricing in-line with other branded NSAIDs, thereby significantly increasing the value we realize per prescription, and also increasing sales and marketing support to drive volume growth in prescriptions. We cannot guarantee that this strategy will continue to be effective generally, due to negative reactions to price increases or otherwise. More recently, we have begun entering into rebate agreements with pharmacy benefit managers, or PBMs, for certain of our primary care medicines where we believe the rebates and costs justify expanded formulary access for patients. However, we cannot guarantee that we will be able to secure additional rebate agreements on commercially reasonable terms. For each of our primary care medicines, we expect that our commercial success will depend on our sales and marketing efforts in the United States.

Our strategy for RAYOS in the United States is to solely focus on the rheumatology indications approved for RAYOS where our Phase 3 clinical trial data supports our commercial plans.

Our overall commercialization strategy also includes plans to expand our sales and market efforts in Europe and other countries outside the United States for certain of our orphan and rheumatology medicines. In November 2015, we received approval of the Committee for Medicinal Products for Human Use of the European Medicines Agency, or EMA, for RAVICTI for use as an adjunctive therapy for chronic management of adult and pediatric UCD patients greater than two months of age. This authorizes us to market RAVICTI in all 28 Member States of the European Union, or EU, and will form the basis for recognition by the Member States of the European Economic Area, namely Norway, Iceland and Liechtenstein, for the medicine to be placed on the market. In June 2016, we partnered with Clinigen Group plc's Idis managed access division to initiate a managed access program in selected European countries. While we expect to commercially launch RAVICTI in Europe in 2017, we cannot guarantee we will be able to successfully implement our commercial plans for RAVICTI in Europe. With respect to PROCYSBI and QUINSAIR, which are approved for marketing in the EU, we intend to continue evaluating commercial launches in additional EU countries as well as pursuing early access programs. Although LODOTRA is approved for marketing in countries outside the United States, to date it has only been marketed in a limited number of countries.

If any of our commercial strategies are unsuccessful or we fail to successfully modify our strategies over time due to changing market conditions, our ability to increase market share for our medicines, grow revenues and sustain profitability will be harmed.

In order to increase adoption and sales of our medicines, we will need to continue developing our commercial organization as well as recruit and retain qualified sales representatives.*

Part of our strategy is to continue to build a biopharmaceutical company to successfully execute the commercialization of our medicines in the U.S. market, and in selected markets in Europe where we have commercial rights. We may not be able to successfully commercialize our medicines in the United States or in any other territories where we have commercial rights. Prior to our commercial launch of DUEXIS in the United States in December 2011, we did not have any experience commercializing medicines on our own. In order to commercialize any approved medicines, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Although we had expanded our sales force to approximately 470 sales representatives as of September 30, 2016, consisting of approximately 15 orphan disease sales representatives, 90 rheumatology sales specialists and 365 primary care sales representatives, we currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market our medicines and any additional medicines we may acquire will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

As a result of the evolving role of various constituents in the prescription decision making process, we adjusted the profile of the sales representatives we hire for our primary care and rheumatology business units from those with traditional pharmaceutical sales experience to those with successful business to business experience. For example, we have faced challenges due to pharmacists increasingly switching a patient's intended prescription from DUEXIS and VIMOVO to a generic or over-the-counter brand of their active ingredients. We have faced similar challenges for RAYOS, BUPHENYL and PENNSAID 2% with respect to generic brands. While we believe the profile of our representatives is better suited for this evolving environment, we cannot be certain that our representatives will be able to successfully protect our market for DUEXIS, PENNSAID 2%, RAYOS, BUPHENYL and VIMOVO or that we will be able to continue attracting and retaining sales representatives with our desired profile and skills. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain commercial personnel. To the extent we rely on additional third parties to commercialize any approved medicines, we may receive less revenue than if we commercialized these medicines ourselves. In addition, we may have little or no control over

the sales efforts of any third parties involved in our commercialization efforts. In the event we are unable to successfully develop and maintain our own commercial organization or collaborate with a third-party sales and marketing organization, we may not be able to commercialize our medicines and medicine candidates and execute on our business plan.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize our medicines will be harmed.*

As we recently acquired additional medicines through acquisition transactions, the members of our sales force may have limited experience promoting these medicines. To the extent we have retained the sales forces promoting recently-acquired medicines, we may not be successful in continuing to retain these employees and we otherwise have limited experience marketing these medicines under our commercial organization. As a result, we are required to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense our medicines. In addition, we must train our sales force to ensure that a consistent and appropriate message about our medicines is being delivered to our potential customers. Our sales representatives may also experience challenges promoting multiple medicines when we call on physicians and their office staff. We have experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire, requiring us to train new sales representatives. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate physicians about the benefits of our medicines and their proper administration and label indication, as well as our patient access programs, our efforts to successfully commercialize our medicines could be put in jeopardy, which could have a material adverse effect on our financial condition, share price and operations.

If we cannot successfully implement our patient access programs or enter into formulary and reimbursement agreements with pharmacy benefit managers in the face of increasing pressure to reduce the price of medications, the adoption of our medicines by physicians, patients and payers may decline.*

There continues to be immense pressure from healthcare payers and PBMs to use less expensive generics or over-the-counter brands instead of branded medicines. For example, some of the largest PBMs placed DUEXIS and VIMOVO on their formulary exclusion lists beginning in January 2015. Additional healthcare plans, including those that contract with these PBMs but use different formularies, may also choose to exclude our medicines from their formularies or restrict coverage to situations where a generic or over-the-counter medicine has been tried first. Many payers and PBMs also require patients to make co-payments for branded medicines, including many of our medicines, in order to incentivize the use of generic or other lower-priced alternatives instead. Legislation enacted in most states in the United States allows, or in some instances mandates, that a pharmacist dispenses an available generic equivalent when filling a prescription for a branded medicine, in the absence of specific instructions from the prescribing physician. Because our medicines (other than BUPHENYL) do not currently have FDA-approved generic equivalents in the United States, we do not believe our medicines should be subject to mandatory generic substitution laws. However, we understand that some pharmacies may attempt to obtain physician authorization to switch prescriptions for DUEXIS or VIMOVO to prescriptions for multiple generic medicines with similar active pharmaceutical ingredients, or APIs, to ensure payment for the medicine if the physician’s prescription for the branded medicine is not immediately covered by the payer, despite such substitution being off-label in the case of DUEXIS and VIMOVO. If these limitations in coverage and other incentives result in patients refusing to fill prescriptions or being dissatisfied with the out-of-pocket costs of their medications, or if pharmacies otherwise seek and receive physician authorization to switch prescriptions, not only would we lose sales on prescriptions that are ultimately not filled, but physicians may be dissuaded from writing prescriptions for our medicines in the first place in order to avoid potential patient non-compliance or dissatisfaction over medication costs, or to avoid spending the time and effort of responding to pharmacy requests to switch prescriptions.

Part of our commercial strategy to increase adoption and access to our medicines in the face of these incentives to use generic alternatives is to offer physicians the opportunity to have patients fill prescriptions through independent pharmacies participating in our HorizonCares patient access program. Through HorizonCares, financial assistance may be available to reduce eligible patients’ out-of-pocket costs for prescriptions filled. Because of this assistance, eligible patients’ out-of-pocket cost for our medicines when dispensed through HorizonCares may be significantly

lower than such costs when our medicines are dispensed outside of the HorizonCares program. However, to the extent physicians do not direct prescriptions currently filled through traditional pharmacies, including those associated with or controlled by PBMs, to pharmacies participating in our HorizonCares program, we may experience a significant decline in DUEXIS, VIMOVO and PENNSAID 2% prescriptions as a result of formulary exclusions, co-payment requirements or other incentives to use lower-priced alternatives to our medicines. Our ability to increase utilization of our patient access programs will depend on physician and patient awareness and comfort with the programs, and we have limited ability to influence whether physicians use our patient access programs to prescribe our medicines or whether patients will agree to receive our medicines through the HorizonCares program. In addition, the HorizonCares program is not available to federal health care program (such as Medicare and Medicaid) beneficiaries. We have also begun to pursue the additional strategy of contracting with PBMs and other payers to secure formulary status and reimbursement for certain of our primary care medicines, which generally require us to pay administrative fees and rebates to the PBMs and other payers for qualifying prescriptions. While we recently announced a business relationship with one of the largest PBMs, CVS Caremark, that has resulted in DUEXIS and VIMOVO being removed from the CVS Caremark 2017 exclusion list, as well as a rebate agreement with another PBM, Prime Therapeutics LLC, or Prime Therapeutics, and we believe these agreements will secure formulary status for certain of our medicines, we cannot guarantee that we will be able to agree to terms with other PBMs and other payers, or that such terms will be commercially reasonable to us. If we are unable to increase adoption of HorizonCares for filling prescriptions of our medicines or to secure formulary status and reimbursement through arrangements with PBMs and other payers, our ability to maintain or increase prescriptions for our medicines could be impaired.

There has been recent negative publicity regarding the use of specialty pharmacies and drug pricing. Our patient access programs are not involved in the prescribing of medicines and are solely to assist in ensuring that when a physician determines one of our medicines offers a potential clinical benefit to their patients and they prescribe one for an eligible patient, financial assistance may be available to reduce the patient's out-of-pocket costs. In addition, all pharmacies that fill prescriptions for our medicines are fully independent, including those that participate in HorizonCares. We do not own or possess any option to purchase an ownership stake in any pharmacy that distributes our medicines, and our relationship with each pharmacy is non-exclusive and arm's length. All of our sales are processed through pharmacies independent of us. Despite this, the recent negative publicity regarding specialty pharmacies may result in physicians being less willing to participate in our patient access programs and thereby limit our ability to increase patient access and adoption of our medicines.

We may also encounter difficulty in forming and maintaining relationships with pharmacies that participate in our patient access programs. We currently depend on a limited number of pharmacies participating in HorizonCares to fulfill patient prescriptions under the HorizonCares program. If these HorizonCares participating pharmacies are unable to process and fulfill the volume of patient prescriptions directed to them under the HorizonCares program, our ability to maintain or increase prescriptions for our medicines will be impaired. The commercialization of our medicines and our operating results could be affected should any of the HorizonCares participating pharmacies choose not to continue participation in our HorizonCares program or by any adverse events at any of those HorizonCares participating pharmacies. For example, pharmacies that dispense our medicines could lose contracts that they currently maintain with managed care organizations, or MCOs, including PBMs. Pharmacies often enter into agreements with MCOs. They may be required to abide by certain terms and conditions to maintain access to MCO networks, including terms and conditions that could limit their ability to participate in patient access programs like ours. Failure to comply with the terms of their agreements with MCOs could result in a variety of penalties, including termination of their agreement, which could negatively impact the ability of those pharmacies to dispense our medicines and collect reimbursement from MCOs for such medicines.

The HorizonCares program may implicate certain state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud. We have a compliance program in place to address adherence with various laws and regulations relating to the selling, marketing and manufacturing of our medicines, as well as certain third-party relationships, including pharmacies. Specifically with respect to pharmacies, the compliance program utilizes a variety of methods and tools to monitor and audit pharmacies, including those that participate in the HorizonCares program, to confirm their activities, adjudication and practices are consistent with our compliance policies and guidance. Despite our compliance efforts, to the extent the HorizonCares program is found to be inconsistent with applicable laws or the pharmacies that participate in our patient access programs do not comply with applicable laws, we may be required to restructure or discontinue such programs, terminate our relationship with certain pharmacies, or be subject to other significant penalties. In November 2015, we received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents and information related to our patient access programs and other aspects of our marketing and commercialization activities. We are unable to predict how long this investigation will continue or its outcome, but we anticipate that we may incur significant costs in connection with the investigation, regardless of the outcome. We 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 our patient access programs and sales and marketing activities may result in damages, fines, penalties or other administrative sanctions against us.

Even if we are successful in increasing the use of our patient access programs, these programs may become too costly for us to maintain if we are unable to maintain or enhance payer reimbursement of our medicines. The aggregate commercial value of our patient access programs for the nine months ended September 30, 2016 was $1,275.2 million. If additional formularies place our medicines on their exclusion lists or increase the co-payments applicable to our medicines, our cost of ensuring that patients have low-cost access to our medicines will increase and our profitability

could decline. If the cost of maintaining our patient access programs increases relative to our sales revenues, we could be forced to reduce the amount of patient financial assistance that we offer or otherwise scale back or eliminate such programs, which could in turn have a negative impact on physicians' willingness to prescribe and patients' willingness to fill prescriptions of our medicines. As an alternative means of ensuring access to our medicines, we have also begun pursuing business arrangements with PBMs and other payers to secure formulary status and reimbursement of our medicines, such as our recently announced arrangements with CVS Caremark and Prime Therapeutics. While we believe that, if successful, this strategy would result in broader inclusion of certain of our primary care medicines on healthcare plan formularies, and therefore increase payer reimbursement and lower our cost of providing patient access programs, these arrangements generally require us to pay administrative and rebate payments to the PBMs and/or other payers. To the extent that we enter into arrangements with PBMs and other payers, we will owe rebate payments not only on prescriptions under plans that currently exclude certain of our medicines from their formulary and for which we provide significant patient assistance to ensure access, but also on prescriptions that are reimbursed by applicable healthcare plans. If our arrangements with PBMs and other payers do not result in increased prescriptions and reductions in our costs to provide our patient access programs that are sufficient to offset the administrative fees and rebate payments to the PBMs and/or other payers, our financial results may be harmed.

If we are unable to successfully implement our commercial plans and facilitate adoption by patients and physicians of any approved medicines through our sales, marketing and commercialization efforts, then we will not be able to generate sustainable revenues from medicine sales which will have a material adverse effect on our business and prospects.

We are solely dependent on third parties to commercialize certain of our medicines outside the United States. Failure of these third parties or any other third parties to successfully commercialize our medicines and medicine candidates in the applicable jurisdictions could have a material adverse effect on our business.*

We rely on Mundipharma International Corporation Limited, or Mundipharma, for commercialization of LODOTRA in various European countries and certain Asian, Latin American, Middle Eastern, African and other countries. We rely on other third-party distributors for commercialization of BUPHENYL (known as AMMONAPS in certain European countries) in certain territories outside the United States for which we currently have rights. We have limited contractual rights to force these third parties to invest significantly in commercialization of LODOTRA or BUPHENYL in our markets. In the event that Mundipharma or our current ex-U.S. distributors for BUPHENYL or any other third-party with any future commercialization rights to any of our medicines or medicine candidates fail to adequately commercialize those medicines or medicine candidates because they lack adequate financial or other resources, decide to focus on other initiatives or otherwise, our ability to successfully commercialize our medicines or medicine candidates in the applicable jurisdictions would be limited, which would adversely affect our business, financial condition, results of operations and prospects. We have had disagreements with Mundipharma under our European agreements and may continue to have disagreements, which could harm commercialization of LODOTRA in Europe or result in the termination of our agreements with Mundipharma. We also rely on Mundipharma's ability to obtain regulatory approval for LODOTRA in certain Asian, Latin American, Middle Eastern, African and other countries. In addition, our agreements with Mundipharma and our agreements with our current ex-U.S. distributors for BUPHENYL may be terminated by either party in the event of a bankruptcy of the other party or upon an uncured material breach by the other party. If these third parties terminated their agreements, we may not be able to secure an alternative distributor in the applicable territory on a timely basis or at all, in which case our ability to generate revenues from the sale of LODOTRA or BUPHENYL outside the United States would be materially harmed.

Our medicines are subject to extensive regulation, and we may not obtain additional regulatory approvals for our medicines.*

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution and other possible activities relating to our medicines and our medicine candidates are, and will be, subject to extensive regulation by the FDA and other regulatory agencies. Failure to comply with FDA and other applicable regulatory requirements may, either before or after medicine approval, subject us to administrative or judicially imposed sanctions.

To market any drugs or biologics outside of the United States, we and current or future collaborators must comply with numerous and varying regulatory and compliance related requirements of other countries. Approval procedures vary among countries and can involve additional medicine testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Applications for regulatory approval, including a marketing authorization application for marketing new drugs in Europe, must be supported by extensive clinical and preclinical data, as well as extensive information regarding

chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable medicine candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the medicine candidate, the disease or the condition that the medicine candidate is designed to target and the regulations applicable to any particular medicine candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. Regulatory authorities could delay, limit or deny approval of a medicine candidate for many reasons, including because they:

- may not deem a medicine candidate to be adequately safe and effective;
- may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we do;
- may not approve the manufacturing processes or facilities associated with our medicine candidates;
- may conclude that we have not sufficiently demonstrated long-term stability of the formulation for which we are seeking marketing approval;

- may change approval policies (including with respect to our medicine candidates' class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Even if we believe that data collected from our preclinical studies, CMC studies and clinical trials of our medicine candidates are promising and that our information and procedures regarding CMC are sufficient, our data may not be sufficient to support marketing approval by regulatory authorities, or regulatory interpretation of these data and procedures may be unfavorable. Even if approved, medicine candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the medicine may be marketed, restricted distribution methods or other limitations. Our business and reputation may be harmed by any failure or significant delay in obtaining regulatory approval for the sale of any of our medicine candidates. We cannot predict when or whether regulatory approval will be obtained for any medicine candidate we develop.

Hyperion Therapeutics, Inc., or Hyperion, submitted a New Drug Submission, or NDS, to Health Canada, or HC, for approval to market RAVICTI in Canada. In March 2016, HC issued a Notice of Compliance for RAVICTI for use as an adjunctive therapy for chronic management of adult and pediatric patients two years of age and older with UCDs, and we launched RAVICTI in Canada in November 2016. However, if we are unable to obtain any further approvals for RAVICTI outside the United States, Canada and Europe, or determine that commercializing RAVICTI outside the United States, Canada and Europe is not economically viable, the market potential of RAVICTI may be limited.

On July 12, 2016, Raptor Pharmaceutical Corp., or Raptor, received a notice of deficiency, or NOD, from HC dated July 11, 2016 relating to the NDS Raptor submitted for PROCYSBI in January 2016. The NOD states that information provided in the NDS is insufficient for HC to complete its review. HC's review of the PROCYSBI NDS will re-commence upon its acceptance of a response to its notice. We submitted our response on November 4, 2016. If HC accepts the response to the NOD as complete, its decision as to whether to grant marketing approval for PROCYSBI for the treatment of nephropathic cystinosis will be delayed due to the NOD and the time to review the response.

With respect to QUINSAIR, the FDA has indicated in previous written and verbal communications with Raptor and with the drug's previous sponsor that it believes the data submitted in connection with EMA's subsequent approval of QUINSAIR for the management of chronic pulmonary infections due to Pseudomonas aeruginosa in adults with cystic fibrosis does not provide substantial evidence of efficacy and safety to support FDA approval of QUINSAIR for treatment of patients with cystic fibrosis. The FDA identified a number of limitations with the design of the Phase 3 trial (MPEX-209) upon which approval of QUINSAIR in the EU and Canada was based that, in the FDA's view, impacts its ability to be used as a pivotal efficacy study. The FDA also previously indicated that the pivotal Phase 3 study (MPEX-207) missed its primary endpoint and questioned whether patients in the study achieved any overall benefit. It is possible that additional studies or analyses may be required prior to a submission of a new drug application, or NDA, for approval of QUINSAIR for treatment of Pseudomonas aeruginosa in adults with cystic fibrosis. In the second quarter of 2016, Raptor met with the FDA to discuss a planned NDA. The FDA had several questions related to the MPEX-209 study, and asked Raptor to submit information prior to any submission of a NDA. Raptor submitted data in response to the FDA's request, and subsequently requested a follow-up meeting to discuss the FDA's assessment of that information. In preliminary meeting responses, the FDA largely reiterated its view that the prior Phase 3 trial would not be sufficient to file or approve an NDA for QUINSAIR. On August 26, 2016, Raptor had a follow-up in-person meeting with the FDA. The FDA stated in its meeting minutes dated September 22, 2016 that it recognizes that there is an unmet medical need for cystic fibrosis, or CF, patients. The FDA also stated that although a discussion about the design of a new trial may be helpful, the FDA was willing to reevaluate the existing data and the analysis presented at the meeting to determine if there is enough evidence to support the filing of an NDA. The FDA stated that it will further discuss some of the issues and will provide feedback to Raptor. In addition, the FDA may request additional information. On October 27, 2016, the FDA expressed its recommendation that an additional clinical trial should be conducted, and noted that if Raptor submits an NDA without conducting an additional clinical trial, the FDA will review the submission to determine whether it is

acceptable for filing. We intend to further evaluate a potential NDA for QUINSAIR and it is possible that we will determine that based on the FDA's guidance, further pursuit of U.S. approval of QUINSAIR as a treatment of Pseudomonas aeruginosa in adults with cystic fibrosis is not warranted.

Prior to our acquisition of Raptor, Raptor planned to pursue a Phase 3 clinical trial of QUINSAIR for use in the indication of bronchiectasis, or BE, not associated with cystic fibrosis. On September 8, 2016, Raptor met the Medicines and Healthcare Products Regulatory Agency, or the MHRA, to discuss non-clinical and clinical development aspects of QUINSAIR for the treatment of BE. On September 29, 2016, Raptor received a written response from the MHRA, which included answers to questions on trial design, among other responses. Raptor has also submitted the protocol to the FDA and has not received comments. Raptor was also exploring further clinical development of QUINSAIR for the treatment of pulmonary nontuberculous mycobacteria, or NTM, infection, based on third-party data generated pertaining to the susceptibility of certain pathogens to treatment with levofloxacin and other fluoroquinolone molecules. No clinical data have been generated with QUINSAIR in patients with BE or with NTM infections, either by Raptor, by us or by other parties. This creates uncertainty regarding the potential efficacy of QUINSAIR in these indications.

We will evaluate all development opportunities, including all obligations to use commercial reasonable efforts to further develop QUINSAIR. However, we may determine not to pursue such further development.

The ultimate approval and commercial marketing of any of our medicines in additional indications or geographies is subject to substantial uncertainty. Failure to gain additional regulatory approvals would limit the potential revenues and value of our medicines and could cause our share price to decline.

The amount of our product sales in the European Economic Area, or the EEA, is dependent in part upon the pricing and reimbursement decisions adopted in each of the EEA countries, which may not be at acceptable levels to us.*

One or more EEA countries may not support pricing within our target pricing and reimbursement range for our medicines due to budgetary decisions made by regional, national and local health authorities and third-party payers in the EEA, which would negatively affect our revenues. The pricing and reimbursement process in EEA countries can be lengthy, involved and difficult to predict. Failure to timely complete the pricing and reimbursement process in the EEA countries will delay our ability to market PROCYSBI, to bring QUINSAIR to market in the EEA and to derive revenues from those countries.

We may be subject to penalties and litigation and large incremental expenses if we fail to comply with regulatory requirements or experience problems with our medicines.*

Even after we achieve regulatory approvals, we are subject to ongoing obligations and continued regulatory review with respect to many operational aspects including our manufacturing processes, labeling, packaging, distribution, storage, adverse event monitoring and reporting, dispensation, advertising, promotion and recordkeeping. These requirements include submissions of safety and other post-marketing information and reports, ongoing maintenance of product registration and continued compliance with current good manufacturing practices, or cGMPs, good clinical practices, or GCPs, good pharmacovigilance practice, good distribution practices and good laboratory practices, or GLPs. If we, our medicines or medicine candidates, or the third-party manufacturing facilities for our medicines or medicine candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose injunctions or restrictions on the marketing, manufacturing or distribution of a product, suspend or withdraw product approvals, revoke necessary licenses or suspend product reimbursement;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- suspend any ongoing clinical trials or delay or prevent the initiation of clinical trials;
- delay or refuse to approve pending applications or supplements to approved applications we have filed;
- refuse to permit drugs or precursor or intermediary chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions or additional requirements on operations, including costly new manufacturing quality or pharmacovigilance requirements;
- seize or detain products or require us to initiate a product recall; and/or
- commence criminal investigations and prosecutions.

Moreover, existing regulatory approvals and any future regulatory approvals that we obtain will be subject to limitations on the approved indicated uses and patient populations for which our medicines may be marketed, the conditions of approval, requirements for potentially costly, post-market testing and requirements for surveillance to monitor the safety and efficacy of the medicines. In the EEA, the advertising and promotion of pharmaceuticals is strictly regulated. The direct-to-consumer promotion of prescription pharmaceuticals is not permitted, and some countries in the EEA require the notification and/or prior authorization of promotional or advertising materials directed at healthcare professionals. The FDA, EMA and other authorities in the EEA countries strictly regulate the promotional claims that may be made about prescription products, and our product labeling, advertising and

promotion are subject to continuing regulatory review. Physicians nevertheless may prescribe our medicines to their patients in a manner that is inconsistent with the approved label or that is off-label. Positive clinical trial results in any of our medicine development programs increase the risk that approved pharmaceutical forms of the same active pharmaceutical ingredients may be used off-label in those indications. Our investigational medicine candidate RP103 is comprised of the same API as PROCYSBI. If we are found to have improperly promoted off-label uses of approved medicines, we may be subject to significant sanctions, civil and criminal fines and injunctions prohibiting us from engaging in specified promotional conduct.

In addition, engaging in improper promotion of our medicines for off-label uses in the United States can subject us to false claims litigation under federal and state statutes. These false claims statutes in the United States include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims or causing to present such false or fraudulent claims for payment by a federal program such as Medicare or Medicaid. Growth in false claims litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay civil money penalties, settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs.

The regulations, policies or guidance of regulatory agencies may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our medicine candidates or further restrict or regulate post-approval activities. For example, the Food and Drug Administration Safety and Innovation Act requires the FDA to issue new guidance describing its policy regarding internet and social media promotion of regulated medical products, and the FDA may soon specify new restrictions on this type of promotion. In January 2014, the FDA released draft guidance on how drug companies can fulfill their regulatory requirements for post-marketing submission of interactive promotional media, and though the guidance provided insight into how the FDA views a company’s responsibility for certain types of social media promotion, there remains a substantial amount of uncertainty. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are unable to achieve and maintain regulatory compliance, we will not be permitted to market our drugs, which would materially adversely affect our business, results of operations and financial condition.

Our limited history of commercial operations makes evaluating our business and future prospects difficult and may increase the risk of any investment in our ordinary shares.*

We face considerable risks and difficulties as a company with limited commercial operating history, particularly as a global consolidated entity with operating subsidiaries that also have limited operating histories. If we do not successfully address these risks, our business, prospects, operating results and financial condition will be materially and adversely harmed. Our limited commercial operating history, including our limited history commercializing our current medicines, makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. For example, we may underestimate the resources we will require to successfully integrate recent or future medicine or company acquisitions, or to commercialize our medicines, or not realize the benefits we expect to derive from our recent or future acquisitions. In addition, we have a limited history implementing our commercialization strategy focused on patient access, and we cannot guarantee that we will be able to successfully implement this strategy or that it will represent a viable strategy over the long term.

We have rights to medicines in certain jurisdictions but have no control over third parties that have rights to commercialize those medicines in other jurisdictions, which could adversely affect our commercialization of these medicines.*

Boehringer Ingelheim International GmbH, or Boehringer Ingelheim International, currently has certain rights to commercialize interferon gamma 1b, known as IMUKIN, outside the United States, Canada and Japan. On May 18, 2016, we entered into a definitive agreement with Boehringer Ingelheim International to acquire such rights to IMUKIN, or the IMUKIN Acquisition. The transaction is expected to close in the first half of 2017 and we are continuing to work with Boehringer Ingelheim International to enable the transfer of applicable marketing authorizations. AstraZeneca AB, or AstraZeneca, has retained its existing rights to VIMOVO in territories outside of the United States, including the right to use the VIMOVO name and related trademark. While we have the worldwide rights to BUPHENYL, the marketing and distribution rights are licensed to Swedish Orphan Biovitrum AB, or SOBI, through the end of 2016. Similarly, Nuvo Research Inc., or Nuvo, has retained its rights to PENNSAID 2% in territories outside of the United States and has announced its intention to seek commercialization partners outside the United States. We have little or no control over Boehringer Ingelheim International's activities with respect to IMUKIN outside the United States, Canada and Japan, over AstraZeneca's activities with respect to VIMOVO outside of the United States, over SOBI's activities with respect to BUPHENYL in Europe, certain Asian, Latin American, Middle Eastern, North African and other countries or over Nuvo's or its future commercial partners' activities with respect to PENNSAID 2% outside of the United States, even though those activities could impact our ability to successfully commercialize ACTIMMUNE, VIMOVO, BUPHENYL and PENNSAID 2%. For example, AstraZeneca or its assignees or Nuvo or its assignees can make statements or use promotional materials with respect to VIMOVO or PENNSAID 2%, respectively, outside of the United States that are inconsistent with our positioning of the medicines in the United States, and could sell VIMOVO or PENNSAID 2%, respectively, in foreign countries, including Canada, at prices that are dramatically lower than the prices we charge in the United States. These activities and decisions, while occurring outside of the United States, could harm our commercialization strategy in the United States, in particular because AstraZeneca is continuing to market VIMOVO outside the United States under the same VIMOVO brand name that we are using in the United States. In addition, medicine recalls or safety issues with ACTIMMUNE, VIMOVO, BUPHENYL or PENNSAID 2% outside the United States, even if not related to the commercial medicine we sell in the United States, could result in serious damage to the brand in the United States and impair our ability to successfully market ACTIMMUNE, VIMOVO, BUPHENYL and PENNSAID 2%. We also rely on Boehringer Ingelheim International, AstraZeneca, SOBI and Nuvo or their assignees to provide us with timely and accurate safety information regarding the use of ACTIMMUNE, VIMOVO, BUPHENYL or PENNSAID 2%, respectively, outside of the United States (and outside of Canada and Japan with regards to Boehringer Ingelheim International), as we have or will have limited access to this information ourselves.

We rely on third parties to manufacture commercial supplies of all of our medicines, and we currently intend to rely on third parties to manufacture commercial supplies of any other approved medicines. The commercialization of any of our medicines could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of medicine or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.*

The facilities used by our third-party manufacturers to manufacture our medicines and medicine candidates must be approved by the applicable regulatory authorities. We do not control the manufacturing processes of third-party manufacturers and are currently completely dependent on our third-party manufacturing partners. In addition, we are required to obtain AstraZeneca's consent prior to engaging any third-party manufacturers for esomeprazole, one of the APIs in VIMOVO, other than the third-party manufacturer(s) used by AstraZeneca or its affiliates or licensees. To the extent such manufacturers are unwilling or unable to manufacture esomeprazole for us on commercially acceptable terms, we cannot guarantee that AstraZeneca would consent to our use of alternate sources of supply.

We rely on an exclusive supply agreement with Boehringer Ingelheim RCV GmbH & Co. KG, or Boehringer Ingelheim, for manufacturing and supply of ACTIMMUNE. However, Boehringer Ingelheim also currently manufactures interferon gamma-1b to supply its own commercial needs in its licensed territory, and this may lead to capacity allocation issues and supply constraints to our company. On May 18, 2016, we entered into a definitive agreement with Boehringer Ingelheim International to acquire their rights to interferon gamma-1b, which is expected to close in the first half of 2017, and we are continuing to work with Boehringer Ingelheim International to enable the transfer of applicable marketing authorizations. ACTIMMUNE is manufactured by starting with cells from working cell bank samples which are derived from a master cell bank. We and Boehringer Ingelheim separately store multiple vials of the master cell bank. In the event of catastrophic loss at our or Boehringer Ingelheim's storage facility, it is possible that we could lose multiple cell banks and have the manufacturing capacity of ACTIMMUNE severely impacted by the need to substitute or replace the cell banks. In addition, a key excipient used in PENNSAID 2% as a penetration enhancer is dimethyl sulfoxide, or DMSO. We and Nuvo, our exclusive supplier of PENNSAID 2%, rely on a sole proprietary form of DMSO for which we maintain a substantial safety stock. However, should this supply become inadequate, damaged, destroyed or unusable, we and Nuvo may not be able to qualify a second source. We rely on NOF Corporation, or NOF, as our exclusive supplier of the PEGylation agent that is a critical raw material in the manufacture of KRYSTEXXA. If NOF failed to supply such PEGylation agent, it may lead to KRYSTEXXA supply constraints.

If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. For example, Pharmaceutics International, Inc., or PII, our manufacturer of BUPHENYL, was found to be non-compliant for cGMPs by the MHRA, which could restrict PII from supplying BUPHENYL in the EU. However, BUPHENYL was considered to be critical to public health and as a result, the MHRA issued a certificate of cGMP compliance for PII which is valid until June 30, 2017. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve these facilities for the manufacture of our medicines or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to supply our primary active ingredients or manufacture our medicines, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our medicines. To the extent any third-party manufacturers that we engage with respect to our medicines are different from those currently being used for commercial supply in the United States, the FDA will need to approve the facilities of those third-party manufacturers used in the manufacture of our medicines prior to our sale of any medicine using these facilities.

Although we have entered into supply agreements for the manufacture of our medicines, our manufacturers may not perform as agreed or may terminate their agreements with us. Under our manufacturing and supply agreement with Sanofi-Aventis U.S. LLC, or Sanofi-Aventis U.S., either we or Sanofi-Aventis U.S. may terminate the agreement upon an uncured breach by the other party or without cause upon two years prior written notice. Under our master manufacturing services and medicine agreement with Patheon Pharmaceuticals Inc., or Patheon, for finished VIMOVO medicine, either we or Patheon may terminate the agreement for uncured material breach by the other party or upon the other party's bankruptcy or insolvency, we may terminate the agreement if any regulatory authority takes any action or raises any objection that prevents us from commercializing the VIMOVO medicine and Patheon may terminate the agreement if we assign our rights or obligations under the agreement to a competitor of Patheon or to a party that, in the reasonable opinion of Patheon, is not a credit worthy substitute for us, or in certain other circumstances where we assign the agreement without Patheon's consent. Our manufacturing agreement with Boehringer Ingelheim has a term that runs until July 31, 2020, but the agreement may be terminated earlier by either us or Boehringer Ingelheim for an uncured material breach by the other party or upon the other party's bankruptcy or insolvency. Under our manufacturing and supply agreement with Jagotec AG, or Jagotec, either we or Jagotec may terminate the agreement in the event of an insolvency, liquidation or bankruptcy of the other party or upon an uncured breach by the other party. While we have the right to receive a continuing supply of RAYOS/LODOTRA from Jagotec for a period of 24 months after termination, we would need to move our manufacturing to our alternate supplier of RAYOS/ LODOTRA, Bayer Pharma AG, in such an event and we may have to qualify a new back-up manufacturer. The term of our supply agreement with Nuvo for PENNSAID 2% 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. With respect to BUPHENYL, our supply agreement with PII is in place until April 1, 2017, however, the agreement may be terminated earlier by either party. The term of our manufacturing agreement with Halo Pharmaceutical, Inc. for RAVICTI runs until July 4, 2018, however, the agreement may be terminated earlier in the case of breach by either party if the other party is in material breach of any provision of the agreement and the other party fails to remedy such a breach within thirty days, or by us at any time for any reason. Our master services agreement with Lyne Laboratories, Inc., or Lyne, for RAVICTI runs until February 1, 2017, with provision for 12 monthly auto renewals thereafter, unless 6 months' written notice is provided by either party. The agreement may be terminated earlier, on 30 days' notice, in case of breach by either party. The term of our commercial supply agreement with Bio-Technology General (Israel) Ltd., or BTG Israel, for KRYSTEXXA bulk product 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. We currently rely on single source suppliers for cysteamine API and for PROCYSBI drug product. We also rely on single source suppliers for the QUINSAIR API and drug product and the base units, nebulizers and hand-held devices used for the administration of QUINSAIR.

Our supply agreement with Cambrex Profarmaco Milano, or Cambrex, for cysteamine API runs until November 3, 2020, and will automatically renew for successive two year periods after such initial term. The agreement may be terminated earlier by either party for any uncured material breach or upon one year advance notice by either party provided such notice is given at least one year prior to the expiration of the then-current term. We are also be able to terminate the agreement in the event of certain supply failures by Cambrex or if we determined that the products incorporating the cysteamine API will not be marketed or the FDA or EMA withdraws approval or fails to approve such products then in development. Our supply agreement for QUINSAIR API runs, with respect to the United States, until the seventh anniversary after the first commercial sale in the United States, with respect to Europe, until the fifth anniversary after the first commercial sale in Europe, in each case subject to early termination under specified circumstances. Our commercial supply agreement with PARI Pharma GmbH, or PARI, for base units, nebulizers and hand-held devices used for the administration of QUINSAIR may be terminated by either party for any uncured material breach by the other party of its obligations under the agreement, upon the filing of an application for commencement of bankruptcy or similar proceeding against the other party, or if we cease development and commercialization of applicable products for a certain number of years. We rely on safety stock to mitigate the risk of our current suppliers electing to cease producing bulk drug medicine or ceasing to do so at acceptable prices and quality. However, we can provide no assurance that such safety stocks would be sufficient to avoid supply shortfalls in the event we have to identify and qualify new contract manufacturers.

In addition, we do not have the capability to package any of our medicines for distribution. Under our master manufacturing services agreement with Patheon, we have entered into an agreement for packaging of RAYOS/LODOTRA. Valeant Pharmaceuticals International, Inc. manufactures and supplies DUEXIS to us in final, packaged form for the United States as well as any additional countries as may be agreed to by the parties. Patheon supplies final, packaged VIMOVO medicine pursuant to the master manufacturing services and product agreement we executed in connection with our acquisition of the U.S. rights to VIMOVO. Boehringer Ingelheim supplies final, packaged ACTIMMUNE to us and Nuvo supplies final, packaged PENNSAID 2% to us, in each case under exclusive supply agreements. We have clinical and commercial supplies of BUPHENYL finished medicine manufactured for us by PII on a purchase order basis. We have clinical and commercial supplies of RAVICTI finished drug medicine manufactured by Lyne under a commercial supply agreement and have an agreement in place with Halo Pharmaceutical, Inc. to serve as a finished drug medicine supplier for RAVICTI in the EU. Sigma Tau PharmaSource Inc. supplies final, packaged KRYSTEXXA to us for the United States. G & W Laboratories, Inc. manufactures and supplies MIGERGOT to us in final, packaged form for the United States.

The manufacture of medicines requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medicines often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the medicine, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in the medicines or in the manufacturing facilities in which our medicines are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that issues relating to the manufacture of any of our medicines will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize our medicines in the United States or provide any medicine candidates to patients in clinical trials would be jeopardized.

Any delay or interruption in our ability to meet commercial demand for our medicines will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these medicines. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase

the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our medicines or medicine candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

We have experienced recent growth and expanded the size of our organization substantially in connection with our recent acquisition transactions, and we may experience difficulties in managing this growth as well as potential additional growth in connection with future medicine or company acquisitions.*

As of December 31, 2010 and prior to the commercial launch of DUEXIS, we employed approximately 40 full-time employees as a consolidated entity. As of September 30, 2016, we employed approximately 870 full-time employees, including approximately 470 sales representatives, representing a substantial change to the size of our organization over a relatively short period of time. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire in connection with the commercialization of our medicines, requiring us to hire and train new sales representatives. Our management, personnel, systems and facilities currently in place may not be adequate to support this recent and anticipated growth, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses.

As our commercialization plans and strategies continue to develop, we will need to continue to recruit and train sales and marketing personnel and expect to need to expand the size of our employee base for managerial, operational, financial and other resources as a result of our recent acquisitions. Our ability to manage any future growth effectively may require us to, among other things:

- continue to manage and expand the sales and marketing efforts for our existing medicines;
- enhance our operational, financial and management controls, reporting systems and procedures;
- expand our international resources;
- successfully identify, recruit, hire, train, maintain, motivate and integrate additional employees;
- establish and increase our access to commercial supplies of our medicines and medicine candidates;
- expand our facilities and equipment; and
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators, distributors and other third parties.

In particular, the merger of our business with the business of Vidara Therapeutics International Public Limited Company, or Vidara, is subject to numerous uncertainties and risks and will continue to require significant efforts and expenditures. For example, we have transitioned from a standalone public Delaware corporation to being part of a combined company organized in Ireland. This combination as well as our other recent acquisitions have resulted in many changes, including significant changes in the corporate business and legal entity structure, the integration of other companies and their personnel with us, and changes in systems. We are currently undertaking numerous complex transition activities associated with our recent acquisitions, and we may encounter unexpected difficulties or incur unexpected costs, including:

- difficulties in achieving growth prospects from combining third party businesses with our business;
- difficulties in the integration of operations and systems;
- difficulties in the assimilation of employees and corporate cultures;
- challenges in preparing financial statements and reporting timely results at both a statutory level for multiple entities and jurisdictions and at a consolidated level for public reporting;
- challenges in keeping existing physician prescribers and patients and increasing adoption of acquired medicines;
- difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects from the combination;
- potential unknown liabilities, adverse consequences and unforeseen increased expenses associated with the transaction; and
- challenges in attracting and retaining key personnel.

If any of these factors impair our ability to continue to integrate our operations with those of any companies or businesses we acquire, we may not be able to realize the business opportunities, growth prospects and anticipated tax synergies from combining the businesses. In addition, we may be required to spend additional time or money on

integration that otherwise would be spent on the development and expansion of our business.

As a result of our acquisition of Raptor and our plans to launch RAVICTI in Europe, we also expect to continue expanding our operations and to add commercial personnel in Europe. We may not be successful in integrating Raptor's existing European operations and personnel with our own or in otherwise growing our commercial operations outside the United States, and could encounter other challenges in growing our commercial presence in Europe, including due to risks associated with political and economic instability, operating under different legal requirements and tax complexities. If we are unable to manage our commercial growth outside of the Unites States, our opportunities to expand sales in other countries will be limited or we may experience greater costs with respect to our ex-U.S. commercial operations.

Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities and toward managing these growth and integration activities. Our future financial performance and our ability to execute on our business plan will depend, in part, on our ability to effectively manage any future growth and our failure to effectively manage growth could have a material adverse effect on our business, results of operations, financial condition and prospects.

We face significant competition from other biotechnology and pharmaceutical companies, including those marketing generic medicines and our operating results will suffer if we fail to compete effectively.*

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and international markets, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Additional consolidations in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors and we will have to find new ways to compete and may have to potentially merge with or acquire other businesses to stay competitive. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or in-licensing on an exclusive basis, medicines that are more effective and/or less costly than our medicines.

DUEXIS and VIMOVO face competition from other NSAIDs, including Celebrex®, which was marketed by Pfizer Inc., and is also a generic medicine known as celecoxib and marketed by other pharmaceutical companies. DUEXIS and VIMOVO also face significant competition from the separate use of NSAIDs for pain relief and GI protective medications to reduce the risk of NSAID-induced upper GI ulcers. Both NSAIDs and GI protective medications are available in generic form and may be less expensive to use separately than DUEXIS or VIMOVO. PENNSAID 2% faces competition from generic versions of diclofenac sodium topical solutions that are priced significantly less than the price we charge for PENNSAID 2%, and Voltaren Gel, marketed by Endo Pharmaceuticals Solutions Inc., which is the market leader in the topical NSAID category. Legislation enacted in most states in the United States allows, or in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded medicine, in the absence of specific instructions from the prescribing physician. Because pharmacists often have economic and other incentives to prescribe lower-cost generics, if physicians prescribe DUEXIS, PENNSAID 2% or VIMOVO, those prescriptions may not result in sales. If physicians do not complete prescriptions through our HorizonCares program or otherwise provide prescribing instructions prohibiting the substitution of generic ibuprofen and famotidine separately as a substitution for DUEXIS or generic naproxen and branded Nexium® (esomeprazole) as a substitute for VIMOVO or generic diclofenac sodium topical solutions as a substitute for PENNSAID 2%, sales of DUEXIS, PENNSAID 2% and VIMOVO may suffer despite any success we may have in promoting DUEXIS, PENNSAID 2% or VIMOVO to physicians. In addition, other medicine candidates that contain ibuprofen and famotidine in combination or naproxen and esomeprazole in combination, while not currently known or FDA approved, may be developed and compete with DUEXIS or VIMOVO, respectively, in the future. While KRYSTEXXA faces limited direct competition, a number of competitors have drugs in Phase 1 or Phase 2 trials. On

December 22, 2015, AstraZeneca secured approval from the FDA for ZURAMPIC (lesinurad) 200mg tablets in combination with a xanthine oxidase inhibitor, or XOI, for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid (sUA) levels with an XOI alone. In April 2016, the U.S. rights to ZURAMPIC were licensed to Ironwood Pharmaceuticals Inc. Although ZURAMPIC is not a direct competitor because it has not been approved for refractory gout, this therapy could be used prior to use of KRYSTEXXA and if effective, could reduce the target patient population for KRYSTEXXA. PROSCYSBI faces competition from Cystagon (immediate-release cysteamine bitartrate capsules) for the treatment of cystinosis and Cystaran (cysteamine ophthalmic solution) for treatment of corneal crystal accumulation in patients with cystinosis. QUINSAIR faces competition from Tobramycin solution, which is available as a generic medicine for treatment of chronic Pseudomonas aeruginosa lung infections in patients with CF, TOBI Podhaler, Cayston and colistimethate.

We have also entered into settlement and license agreements that may allow certain of our competitors to sell generic versions of certain of our medicines in the United States, subject to the terms of such agreements. On August 21, 2013, we entered into a settlement agreement, or the Par settlement agreement, and license agreement, or the Par license agreement, with Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., or collectively Par, relating to our patent infringement litigation with Par. Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances), or the License, to manufacture and commercialize Par's generic version of DUEXIS in the United States after the generic entry date (as defined below) and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par's generic version of DUEXIS prior to the generic entry date. Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of potential future third-party DUEXIS patent litigation, the entry of other third-party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. Only in the event that Par enters the DUEXIS market due to the specified changes in DUEXIS market conditions will the License become royalty-bearing, with the royalty obligations ceasing upon the occurrence of one of the other events that would have allowed Par to enter the DUEXIS market.

On May 6, 2015, we entered into a settlement and license agreement, or the Perrigo settlement agreement, with Perrigo Company plc and its subsidiary Paddock Laboratories, LLC, or collectively Perrigo, relating to patent infringement litigation with Perrigo. Under the Perrigo settlement agreement, we granted Perrigo a non-exclusive license to manufacture and commercialize Perrigo's generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Perrigo's generic version of PENNSAID 2% during certain limited periods prior to the license effective date. Under the Perrigo settlement agreement, the license effective date is January 10, 2029; however, Perrigo may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in our PENNSAID 2% shipments over specified periods of time. In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, we may be required to supply PENNSAID 2% to Perrigo as our authorized distributor of generic PENNSAID 2%, with us receiving specified percentages of any net sales by Perrigo. We also agreed that if we enter into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, we will amend the Perrigo settlement agreement to provide Perrigo with terms that are no less favorable than those provided to the other parties.

On September 9, 2015, we entered into a settlement and license agreement, or the Taro settlement agreement, with Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd., or collectively Taro, relating to patent infringement litigation with Taro. Under the Taro settlement agreement, we granted Taro a non-exclusive license to manufacture and commercialize Taro's generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Taro's generic version of PENNSAID 2% during certain limited periods prior to the license effective date. Under the Taro settlement agreement, the license effective date is January 10, 2029; however, Taro may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in our PENNSAID 2% shipments over specified periods of time. We also agreed that if we enter into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, we will amend the Taro settlement agreement to provide Taro with terms that are no less favorable than those provided to the other parties.

On October 1, 2015, we, as well as Jagotec, entered into a license and settlement agreement, or the Actavis settlement agreement, with Actavis Laboratories FL, Inc. (formerly known as Watson Laboratories, Inc. – Florida), or Actavis FL, relating to patent infringement litigation with Actavis FL. Under the Actavis settlement agreement, we and Jagotec granted Actavis FL a non-exclusive license to manufacture and commercialize Actavis FL's generic version of

RAYOS tablets in the United States after the generic entry date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Actavis FL's generic version of RAYOS tablets during certain limited periods prior to the generic entry date. We and Jagotec also agreed that during the 180 days after the generic entry date, the license granted to Actavis FL would be exclusive with respect to any third-party generic version of RAYOS tablets. Under the Actavis settlement agreement, the generic entry date is December 23, 2022; however, Actavis FL may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party RAYOS patent litigation, the entry of other generic versions of RAYOS tablets or certain substantial reductions in RAYOS prescriptions over specified periods of time. If we or Jagotec enter into any similar agreements with other parties with respect to generic versions of RAYOS tablets, we and Jagotec agreed to amend the Actavis settlement agreement to provide Actavis FL with terms that are no less favorable than those provided to the other parties with respect to the license terms, generic entry date, permitted pre-market activities and notice provisions.

On April 18, 2016, we entered into a settlement and license agreement, or the Amneal settlement agreement, with Amneal Pharmaceuticals LLC, or Amneal, relating to patent infringement litigation with Amneal. Under the Amneal settlement agreement, we granted Amneal a non-exclusive license to manufacture and commercialize Amneal's generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Amneal's generic version of PENNSAID 2% during certain limited periods prior to the license effective date. Under the Amneal settlement agreement, the license effective date is January 10, 2029; however, Amneal may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation or the entry of other third-party generic versions of PENNSAID 2%. In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, we may be required to supply PENNSAID 2% to Amneal as our non-exclusive, authorized distributor of generic PENNSAID 2%, with us receiving specified percentages of any net sales by Amneal. We also agreed that if we enter into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, we will amend the Amneal settlement agreement to provide Amneal with terms that are no less favorable than those provided to the other parties.

On May 9, 2016, we entered into a settlement and license agreement, or the Teligent settlement agreement, with Teligent, Inc., formerly known as IGI Laboratories, Inc., or Teligent, relating to patent infringement litigation with Teligent. Under the Teligent settlement agreement, we granted Teligent a non-exclusive license to manufacture and commercialize Taro's generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Teligent's generic version of PENNSAID 2% during certain limited periods prior to the license effective date. Under the Teligent settlement agreement, the license effective date is January 10, 2029; however, Teligent may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in our PENNSAID 2% shipments over specified periods of time. We also agreed that if we enter into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, we will amend the Teligent settlement agreement to provide Taro with terms that are no less favorable than those provided to the other parties.

Patent litigation is currently pending in the United States District Court for the District of New Jersey against several companies intending to market a generic version of PENNSAID 2% prior to the expiration of certain of our patents listed in the FDA's Orange Book, or the Orange Book. These cases are collectively known as the PENNSAID 2% cases, and involve the following sets of defendants: (i) Actavis Laboratories UT, Inc., formerly known as Watson Laboratories, Inc., Actavis, Inc. and Actavis plc, or collectively Actavis; and (ii) Lupin Limited and Lupin Pharmaceuticals, Inc., or collectively Lupin. These cases arise from Paragraph IV Patent Certification notice letters from each of Actavis and Lupin advising each had filed an Abbreviated New Drug Application , or ANDA, with the FDA seeking approval to market a generic version of PENNSAID 2% before the expiration of the patents-in-suit. No trial date has been set by the court in these actions.

We received from Actavis a Paragraph IV Patent Certification Notice Letter dated September 27, 2016, against Orange Book listed U.S. Patent No. 9,415,029 advising that Actavis had filed an ANDA with the FDA for a generic version of PENNSAID 2%.

We received from Apotex Inc., or Apotex, a Paragraph IV Patent Certification Notice Letter dated April 1, 2016, against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, 8,871,809, 9,066,913, 9,101,591, 9,132,110, 9,168,304, 9,168,305 and 9,220,784, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%. We also received from Apotex a second Paragraph IV Patent Certification Notice Letter dated June 30, 2016, against Orange Book listed U.S. Patent Nos. 9,339,551 and 9,339,552, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%. We also received from Apotex a third Paragraph IV Patent Certification Notice Letter dated September 21, 2016, against

Orange Book listed U.S. Patent No. 9,415,029, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%.

Patent litigation is currently pending in the United States District Court for the District of New Jersey against several companies intending to market a generic version of VIMOVO before the expiration of certain of our patents listed in the Orange Book. These cases 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., or collectively Dr. Reddy's; (ii) Lupin; (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc., or collectively Mylan; and (iv) Actavis FL and Actavis Pharma, Inc., or collectively Actavis Pharma. The cases arise from Paragraph IV Patent Certification notice letters from each of Dr. Reddy's, Lupin, Mylan and Actavis Pharma advising each had filed an ANDA with the FDA seeking approval to market generic versions of VIMOVO before the expiration of the patents-in-suit.

Patent litigation is currently pending in the United States District Court for the Eastern District of Texas against Par Pharmaceutical, Inc., or Par Pharmaceutical, and in the United States District Court for the District of New Jersey against Par Pharmaceutical and against Lupin, who are each intending to market generic versions of RAVICTI prior to the expiration of certain of our patents listed in the Orange Book. These cases are collectively known as the RAVICTI cases and arise from Paragraph IV Patent Certification notice letters from each of Par Pharmaceutical and Lupin advising each had filed an ANDA with the FDA seeking approval to market a generic version of RAVICTI before the expiration of the patents-in-suit.

If we are unsuccessful in any of the VIMOVO cases or PENNSAID 2% cases, we will likely face generic competition with respect to VIMOVO and/or PENNSAID 2% and sales of VIMOVO and/or PENNSAID 2% will be substantially harmed. If we are unsuccessful in any of the RAVICTI cases, RAVICTI would likely face generic competition in the United States when its orphan exclusivity expires (currently scheduled to occur in February 2020), and its sales would likely materially decline.

ACTIMMUNE is the only medicine currently approved by the FDA specifically for the treatment of CGD and SMO. While there are additional or alternative approaches used to treat patients with CGD and SMO, there are currently no medicines on the market that compete directly with ACTIMMUNE. A widely accepted protocol to treat CGD in the United States is the use of concomitant "triple prophylactic therapy" comprising ACTIMMUNE, an oral antibiotic agent and an oral antifungal agent. However, the FDA-approved labeling for ACTIMMUNE does not discuss this "triple prophylactic therapy," and physicians may choose to prescribe one or both of the other modalities in the absence of ACTIMMUNE. Because of the immediate and life-threatening nature of SMO, the preferred treatment option for SMO is often to have the patient undergo a bone marrow transplant which, if successful, will likely obviate the need for further use of ACTIMMUNE in that patient. Likewise, the use of bone marrow transplants in the treatment of patients with CGD is becoming more prevalent, which could have a material adverse effect on sales of ACTIMMUNE and its profitability. We are aware of a number of research programs investigating the potential of gene therapy as a possible cure for CGD. Additionally, other companies may be pursuing the development of medicines and treatments that target the same diseases and conditions which ACTIMMUNE is currently approved to treat. As a result, it is possible that our competitors may develop new medicines that manage CGD or SMO more effectively, cost less or possibly even cure CGD or SMO. In addition, U.S. healthcare legislation passed in March 2010 authorized the FDA to approve biological products, known as biosimilars, that are similar to or interchangeable with previously approved biological products, like ACTIMMUNE, based upon potentially abbreviated data packages. Biosimilars are likely to be sold at substantially lower prices than branded medicines because the biosimilar manufacturer would not have to recoup the research and development and marketing costs associated with the branded medicine. Though we are not currently aware of any biosimilar under development, the development and commercialization of any competing medicines or the discovery of any new alternative treatment for CGD or SMO could have a material adverse effect on sales of ACTIMMUNE and its profitability.

BUPHENYL's composition of matter patent protection and orphan drug exclusivity have expired. Because BUPHENYL has no regulatory exclusivity or listed patents, there is nothing to prevent a competitor from submitting an ANDA for a generic version of BUPHENYL and receiving FDA approval. In November 2011, Ampolgen Pharmaceuticals, LLC received FDA approval for a generic version of NaPBA tablets, which may compete with RAVICTI and BUPHENYL in treating UCD. In March 2013, SigmaPharm Laboratories, LLC received FDA approval for a generic version of NaPBA powder, which competes with BUPHENYL and may compete with RAVICTI in treating UCD. In July 2013, Lucane Pharma, or Lucane, received marketing approval from the EMA for taste-masked NaPBA and has announced a distribution partnership in Canada. In January 2015, Lucane announced it had received marketing approval for its taste-masked NaPBA in Canada. We believe Lucane is also seeking approval via an ANDA in the United States. If this ANDA is approved, this formulation may compete with RAVICTI and BUPHENYL in treating UCD in the United States. Generic versions of BUPHENYL to date have been priced at a discount relative to BUPHENYL or RAVICTI, and physicians, patients, or payers may decide that this less expensive alternative is preferable to BUPHENYL and RAVICTI. If this occurs, sales of BUPHENYL and/or RAVICTI could be materially reduced, but we would nevertheless be required to make royalty payments to Ucyclyd Pharma, Inc., or Ucyclyd, and another external party, at the same royalty rates. While Ucyclyd and its affiliates are generally contractually prohibited from developing or commercializing new medicines, anywhere in the world, for the treatment of UCD or hepatic encephalopathy, or HE, which are chemically similar to RAVICTI, they may still develop and commercialize medicines that compete with RAVICTI. For example, medicines approved for indications other than UCD and HE may still compete with RAVICTI if physicians prescribe such medicines off-label for UCD or HE. We are also aware that Orphan Europe SARL, or Orphan Europe, is conducting a clinical trial of carglumic acid to treat some of the

UCD enzyme deficiencies for which RAVICTI was approved. Promethera Biosciences SA has successfully completed Phase I/II trials of its cell-based therapy for the treatment of UCD and plans to conduct a Phase IIb/III clinical trial. Carglumic acid is approved for maintenance therapy for chronic hyperammonemia and to treat hyperammonenic crises in Nacetylglutamate synthase deficiency, a rare UCD subtype, and is sold under the name Carbaglu. If the results of this trial are successful and Orphan Europe is able to complete development and obtain approval of Carbaglu to treat additional UCD enzyme deficiencies, RAVICTI would face additional competition from this compound.

The availability and price of our competitors' medicines could limit the demand, and the price we are able to charge, for our medicines. We will not successfully execute on our business objectives if the market acceptance of our medicines is inhibited by price competition, if physicians are reluctant to switch from existing medicines to our medicines, or if physicians switch to other new medicines or choose to reserve our medicines for use in limited patient populations.

In addition, established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to acquire novel compounds that could make our medicines obsolete. Our ability to compete successfully with these companies and other potential competitors will depend largely on our ability to leverage our experience in clinical, regulatory and commercial development to:

- develop and acquire medicines that are superior to other medicines in the market;
- attract qualified clinical, regulatory, and sales and marketing personnel;

- obtain patent and/or other proprietary protection for our medicines and technologies;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicine candidates.

If we are unable to maintain or realize the benefits of orphan drug exclusivity, we may face increased competition with respect to certain of our medicines.*

Under the Orphan Drug Act of 1983, the FDA may designate a medicine as an orphan drug if it is a drug intended to treat a rare disease or condition affecting fewer than 200,000 people in the United States. A company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years from the date of its approval. RAVICTI, KRYSTEXXA and PROSCYSBI have been granted orphan drug exclusivity by the FDA, which we expect will provide orphan drug marketing exclusivity in the United States until May 2020, February 2018 and December 2020, respectively, with exclusivity for PROCYSBI extending to 2022 for patients ages two to six years. However, despite orphan drug exclusivity, the FDA can still approve another drug containing the same active ingredient and used for the same orphan indication if it determines that a subsequent drug is safer, more effective or makes a major contribution to patient care, and orphan exclusivity can be lost if the orphan drug manufacturer is unable to ensure that a sufficient quantity of the orphan drug is available to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective. In addition, orphan drug exclusivity does not prevent the FDA from approving competing drugs for the same or similar indication containing a different active ingredient. If orphan drug exclusivity is lost and we were unable to successfully enforce any remaining patents covering RAVICTI, KRYSTEXXA or PROSCYSBI, we could be subject to generic competition and revenues from RAVICTI, KRYSTEXXA or PROCYSBI could decrease materially. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as RAVICTI, KRYSTEXXA or PROCYSBI despite orphan drug exclusivity, we may face increased competition and lose market share with respect to these medicines. KRYSTEXXA does not have orphan drug exclusivity in the EU or other regions of the world. RAVICTI will benefit from a period of 10 years of orphan market exclusivity in the EU, concurrently applied to each of the approved six sub-types of the UCDs. This will run concurrently with its marketing exclusivity status. PROCYSBI received marketing authorization in September 2013 from the European Commission, or EC, for marketing in the EU as an orphan medicinal product for the management of proven nephropathic cystinosis. PROCYSBI received seven years of market exclusivity, through 2020 for patients six years and older as an orphan drug in the United States and ten years of market exclusivity, through 2023, as an orphan drug in Europe. QUINSAIR received 10 years of market exclusivity in the EU, beginning with its March 2015 marketing authorization. Orphan market exclusivity may be reduced to six years in the EU if the orphan drug designation criteria are no longer met after five years, including where it is shown that the product is sufficiently profitable. As in the United States, loss of orphan marketing exclusivity in the EU may result in early generic competition, which could substantially reduce our revenues from EU sales of these medicines.

Our business operations may subject us to numerous commercial disputes, claims and/or lawsuits and such litigation may be costly and time-consuming and could materially and adversely impact our financial position and results of operations.*

Operating in the pharmaceutical industry, particularly the commercialization of medicines, involves numerous commercial relationships, complex contractual arrangements, uncertain intellectual property rights, potential product liability and other aspects that create heightened risks of disputes, claims and lawsuits. In particular, we may face claims related to the safety of our medicines, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture-related matters. For example, the active ingredient in QUINSAIR, levofloxacin, is currently subject to several product liability claims. Any commercial dispute, claim or lawsuit may

divert management's attention away from our business, we may incur significant expenses in addressing or defending any commercial dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results.

We are currently in litigation with multiple generic drug manufacturers regarding intellectual property infringement. For example, we are currently involved in Hatch Waxman litigation with generic drug manufacturers related to VIMOVO, PENNSAID 2% and RAVICTI.

Similarly, from time to time we are involved in disputes with distributors, PBMs and licensing partners regarding our rights and performance of obligations under contractual arrangements. For example, we were recently in litigation with Express Scripts, Inc., or Express Scripts, related to alleged breach of contract claims and in which Express Scripts was seeking payment for rebates relating to DUEXIS, RAYOS and VIMOVO. We counterclaimed against Express Scripts, contesting the amount owed and contending Express Scripts had breached the rebate agreement. In September 2016, we entered into a settlement agreement and mutual release with Express Scripts pursuant to which we and Express Scripts were released from any and all claims relating to the litigation without admitting any fault or wrongdoing and we agreed to pay Express Scripts $65.0 million.

Litigation related to these disputes may be costly and time-consuming and could materially and adversely impact our financial position and results of operations if resolved against us.

On June 12, 2014, Hyperion acquired Andromeda Biotech Ltd, or Andromeda, an Israeli company developing DiaPep277® for the treatment of recent onset Type 1 diabetes, from Clal Biotechnology Industries Ltd., or CBI. On September 8, 2014, Hyperion announced the termination of further development of DiaPep277 beyond completion of the ongoing clinical trial as a result of evidence Hyperion uncovered that certain employees of Andromeda engaged in serious misconduct that compromised clinical trial results. Hyperion subsequently terminated the Andromeda employees involved in the misconduct and became involved in a legal dispute with CBI related to Andromeda. On February 16, 2015, Hyperion reached a settlement agreement with CBI and Yeda Research and Development Company Ltd., or Yeda, the company from which Andromeda licenses the underlying DiaPep277 technology, to resolve DiaPep277-related claims against one another, and Hyperion granted CBI an option to acquire all of the outstanding stock of Andromeda, or if CBI does not exercise the option, CBI agreed to pay Hyperion $400,000. On September 30, 2015, which was the end of the option exercise period, CBI chose not to exercise its option to acquire all of the outstanding stock of Andromeda. In connection with the settlement agreement, the parties appointed a steering committee to oversee the completion of the clinical trial of DiaPep277 until September 30, 2015, with representatives of CBI and Yeda and a non-voting member appointed by Hyperion. Also on February 16, 2015, Hyperion entered into a release with Evotec International GmbH, or Evotec, pursuant to which Evotec released its previously asserted claims that it was entitled to a milestone payment from Hyperion in connection with Hyperion's acquisition of Andromeda and that it had suffered harm from recent incidents in relation to DiaPep277 in exchange for a payment of $500,000 from Hyperion. In connection with the settlement agreement, CBI transferred to Hyperion beneficial ownership of 96,612 shares of Hyperion common stock. The voluntary liquidation process of Andromeda was approved by the board of its immediate parent Horizon Pharma Israel Holding Corp. Limited in December 2015. In June 2016, the withholding tax certificate was provided to CBI and in July 2016, CBI completed the transfer of shares to Hyperion and made the $400,000 cash payment.

Although the Andromeda release agreements resolved the disputes among the parties relating to DiaPep277, we cannot be certain that additional legal disputes will not arise with respect to Andromeda, including in connection with the completed Phase 3 clinical trial of DiaPep277, the termination of DiaPep277 development by us and the return of related intellectual property to Yeda following CBI's decision to not exercise its option. Further, under the terms of the release agreement, Hyperion agreed to retain certain liabilities relating to its ownership of Andromeda, including any liability related to or based on the misconduct of certain former Andromeda employees that led to its decision to terminate further development of DiaPep277. In addition to these potential liabilities, we may incur currently unknown liabilities related to Hyperion's acquisition of Andromeda. Any such potential legal dispute could lead to costly litigation, divert management's attention from our core business and harm our business.

A variety of risks associated with operating our business and marketing our medicines internationally could materially adversely affect our business.*

In addition to our U.S. operations, we have operations in Ireland, Bermuda, the Grand Duchy of Luxembourg, or Luxembourg, the Netherlands, France, Switzerland, Germany, Canada, the Grand Cayman Islands and in Israel (through Andromeda). Moreover, Grünenthal S.A. is in the registration process for the commercialization of DUEXIS in Latin America. BUPHENYL is currently marketed in various territories outside the United States by third-party distributors. RAVICTI received marketing approval in the EU in November 2015 and we plan to begin commercializing RAVICTI in Europe in 2017. PROCYSBI received marketing authorization from the EMA in September 2013 and is marketed in various countries within the European Economic Area. QUINSAIR received marketing authorization from the EMA in March 2015 and is also marketed in several countries within the European Economic Area. QUINSAIR received marketing authorization from HC in June 2015 and we anticipate launching in Canada in the fourth quarter of 2016. We face risks associated with our international operations, including possible

unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for our medicines;
- compliance with Irish laws and the maintenance of our Irish tax residency with respect to our overall corporate structure and administrative operations, including the need to generally hold meetings of our board of directors and make decisions in Ireland, which may make certain corporate actions more cumbersome, costly and time-consuming;
- difficulties in staffing and managing foreign operations;
- in certain circumstances, including with respect to the commercialization of LODOTRA in Europe and certain Asian, Latin American, Middle Eastern and African countries, commercialization of BUPHENYL in select countries throughout Europe, the Middle East, and the Asia-Pacific region, commercialization of RAVICTI in select countries throughout Europe and commercialization of DUEXIS in Latin America, increased dependence on the commercialization efforts and regulatory compliance of third-party distributors or strategic partners;
- compliance with German laws with respect to our Horizon Pharma GmbH subsidiary through which Horizon Pharma Switzerland GmbH conducts most of its European operations;
- foreign government taxes, regulations and permit requirements;

- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act, or the FCPA;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the United Kingdom's Bribery Act 2010, or the U.K. Bribery Act. The FCPA and similar anti-corruption laws generally prohibit offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to non-U.S. government officials in order to improperly influence any act or decision, secure any other improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the company and to devise and maintain an adequate system of internal accounting controls. The U.K. Bribery Act prohibits giving, offering, or promising bribes to any person, including non-U.K. government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the U.K. Bribery Act, companies which carry on a business or part of a business in the United Kingdom, or U.K., may be held liable for bribes given, offered or promised to any person, including non-U.K. government officials and private persons, by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability is strict, with no element of a corrupt state of mind, but a defense of having in place adequate procedures designed to prevent bribery is available. Furthermore, under the U.K. Bribery Act there is no exception for facilitation payments. As described above, our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, any dealings with these prescribers and purchasers may be subject to regulation under the FCPA. Recently the SEC and the U.S. Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd–Frank Wall Street Reform and Consumer Protection Act, private individuals who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We are engaged in ongoing efforts that are designed to ensure our compliance with these laws, including due diligence, training, policies, procedures and internal controls. However, there is no certainty that all employees and third-party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of manufacturers and other third-party agents, although we may be liable for their actions. Violation of these laws may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

If we fail to develop or acquire other medicine candidates or medicines, our business and prospects would be limited.

A key element of our strategy is to develop or acquire and commercialize a portfolio of other medicines or medicine candidates in addition to our current medicines, through business or medicine acquisitions. Because we do not engage in proprietary drug discovery, the success of this strategy depends in large part upon the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire approved or clinically enabled medicine candidates for therapeutic indications that complement or augment our current medicines, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring promising medicines or medicine candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular medicine or medicine candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire suitable medicines or medicine candidates from third parties or acquire businesses at valuations and on other terms acceptable to us, or if we are unable to raise capital required to acquire businesses or new medicines, our business and prospects will be limited.

Moreover, any medicine candidate we acquire may require additional, time-consuming development or regulatory efforts prior to commercial sale or prior to expansion into other indications, including preclinical studies if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All medicine candidates are prone to the risk of failure that is inherent in pharmaceutical medicine development, including the possibility that the medicine candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such medicines that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

In addition, if we fail to successfully commercialize and further develop our medicines, there is a greater likelihood that we will fail to successfully develop a pipeline of other medicine candidates to follow our existing medicines or be able to acquire other medicines to expand our existing portfolio, and our business and prospects would be harmed.

Our recent medicine and company acquisitions and any other strategic transactions that we may pursue in the future could have a variety of negative consequences, and we may not realize the benefits of such transactions or attempts to engage in such transactions.*

We have recently completed multiple medicine and company acquisitions and our strategy is to engage in additional strategic transactions with third parties, such as acquisitions of companies or divisions of companies and asset purchases of medicines, medicine candidates or technologies that we believe will complement or augment our existing business. We may also consider a variety of other business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and other investments. Any such transaction may require us to incur non-recurring and other charges, increase our near and long-term expenditures, pose significant integration challenges, create additional tax, legal, accounting and operational complexities in our business, require additional expertise, result in dilution to our existing shareholders and disrupt our management and business, which could harm our operations and financial results. For example, in connection with our acquisition of the U.S. rights to VIMOVO, we assumed primary responsibility for the existing patent infringement litigation with respect to VIMOVO, and have also agreed to reimburse certain legal expenses of Pozen Inc., who subsequently entered into a business combination with Tribute Pharmaceuticals Canada Inc. to become known as Aralez Pharmaceuticals Inc., or Aralez, with respect to its continued involvement in such litigation. We also assumed responsibility for the existing patent infringement litigation with respect to RAVICTI upon the closing of the acquisition of Hyperion and have assumed responsibility for completing post-marketing clinical trials of RAVICTI that are required by the FDA and are ongoing. We expect that the RAVICTI litigation will result in substantial on-going expenses and potential distractions to our management team.

In connection with our acquisition of Raptor, we assumed Raptor's post-marketing clinical study obligations in marketing authorization application, or the MAA, for QUINSAIR and contractual obligations under agreements with Tripex Pharmaceuticals, LLC, or Tripex, and PARI related to QUINSAIR. Under the agreement with Tripex, we are required to pursue commercially reasonable efforts to initiate, and subsequently to complete, an additional clinical trial of QUINSAIR in a non-cystic-fibrosis patient population within a specified period of time and an obligation to progress toward filing an NDA for approval of QUINSAIR in the United States in all or part of the cystic fibrosis patient population. These obligations are subject to certain exceptions due to, for example, manufacturing delays not under our control, or delays caused by the FDA. If we fail to properly exercise such efforts to initiate and complete an appropriate clinical trial, or fail to file an NDA for U.S. approval in the cystic fibrosis patient population, during the time periods specified in the asset purchase agreement, we may be subject to various claims by Tripex and parties affiliated with Tripex. In addition, if we do not spend a minimum amount on QUINSAIR development in each of the three years following our acquisition of Raptor, we may also be obligated to pre-pay a milestone payment related to initiating a clinical trial for QUINSAIR in a non-cystic-fibrosis indication. Under the license agreement with PARI, we are required to comply with diligence milestones related to development and commercialization of QUINSAIR in

the United States, to spend a specified minimum amount per year on development activities in the United States until filing of the NDA for QUINSAIR in the United States. If we do not comply with these obligations, our licenses to certain intellectual property related to QUINSAIR may become non-exclusive in the United States or could be terminated. We are also now subject to contractual obligations under license agreements with the University of California, San Diego, or UCSD, with respect to PROCYSBI, including diligence obligations to develop PROCYSBI for the treatment of non-alcoholic steatohepatitis, or NASH, and Huntington's disease, with which we currently are not in compliance. To the extent that we fail to perform the diligence obligations under the agreement, UCSD may, with respect to such indication, terminate the license or otherwise cause the license to become non-exclusive. If one or more of these licenses was terminated, we would have no further right to use or exploit the related intellectual property, which would limit our ability to develop PROCYSBI or QUINSAIR in other indications, and could impact our ability to continue commercializing PROCYSBI or QUINSAIR in their approved indications.

We face significant competition in seeking appropriate strategic transaction opportunities and the negotiation process for any strategic transaction can be time-consuming and complex. In addition, we may not be successful in our efforts to engage in certain strategic transactions because our financial resources may be insufficient and/or third parties may not view our commercial and development capabilities as being adequate. We may not be able to expand our business or realize our strategic goals if we do not have sufficient funding or cannot borrow or raise additional capital. There is no assurance that following any of our recent acquisition transactions or any other strategic transaction, we will achieve the anticipated revenues, net income, tax or other benefits that we believe justify such transactions. In addition, any failures or delays in entering into strategic transactions anticipated by analysts or the investment community could seriously harm our consolidated business, financial condition, results of operations or cash flow.

Our parent company may not be able to successfully maintain its current advantageous tax status and resulting tax rates, which could adversely affect our business and financial condition, results of operations and growth prospects.*

Our parent company is incorporated in Ireland and maintains subsidiaries in multiple jurisdictions, including Ireland, the U.K, the United States, Switzerland, Luxembourg, Germany, Canada and Bermuda. Prior to our merger transaction with Vidara, or the Vidara Merger, Vidara was able to achieve a favorable tax rate through the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions, including Ireland and Bermuda, together with intra-group service and transfer pricing agreements, each on an arm's length basis. We are continuing a substantially similar structure and arrangements. Taxing authorities, such as the U.S. Internal Revenue Service, or IRS, actively audit and otherwise challenge these types of arrangements, and have done so in the pharmaceutical industry. We expect that these challenges will continue as a result of the recent increase in scrutiny and political attention on corporate tax structures. The IRS may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful in defending such a challenge, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our medicines or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The IRS may not agree with our conclusion that our parent company should be treated as a foreign corporation for U.S. federal income tax purposes following the combination of the businesses of Horizon Pharma, Inc. and Vidara Therapeutics International plc.*

Although our parent company is incorporated in Ireland, the IRS may assert that it should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal income tax purposes pursuant to Section 7874 of the Internal Revenue Code of 1986, as amended, or the Code. A corporation is generally considered a tax resident in the jurisdiction of its organization or incorporation for U.S. federal income tax purposes. Because our parent company is an Irish incorporated entity, it would generally be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 provides an exception pursuant to which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal income tax purposes.

Under Section 7874, a foreign corporation will be treated as a U.S. corporation for U.S. federal tax purposes if, due to an acquisition of a U.S. corporation, at least 80 percent of its stock (by vote or value) is held by former stockholders of the acquired U.S. corporation. We believe that we should be treated as a foreign corporation because the former stockholders of Horizon Pharma, Inc., or HPI, owned (within the meaning of Section 7874) less than 80 percent (by both vote and value) of the combined entity's stock immediately after the Vidara Merger. However, there can be no assurance that there will not exist in the future a subsequent change in the facts or in law which might cause our parent

company to be treated as a domestic corporation for U.S. federal income tax purposes, including with retroactive effect.

Further, there can be no assurance that the IRS will agree with the position that the ownership test was satisfied. There is limited guidance regarding the application of Section 7874 of the Code, including with respect to the provisions regarding the application of the ownership test. If our parent company were unable to be treated as a foreign corporation for U.S. federal income tax purposes, one of our significant strategic reasons for completing the Vidara Merger would be nullified and we may not be able to recoup the significant investment in completing the transaction.

Future changes to U.S. and non-U.S. tax laws could materially adversely affect our company.*

Under current law, we expect our parent company to be treated as a foreign corporation for U.S. federal income tax purposes. However, changes to the rules in Section 7874 of the Code or regulations promulgated thereunder or other guidance issued by the U.S. Department of the Treasury, or the U.S. Treasury, or the IRS could adversely affect our parent company’s status as a foreign corporation for U.S. federal income tax purposes, and any such changes could have prospective or retroactive application. If our parent company is treated as a domestic corporation, more of our income will be taxed by the United States which may substantially increase our effective tax rate.

On April 4, 2016, the U.S. Treasury and the IRS issued temporary regulations that expand the scope of transactions subject to the rules designed to eliminate the U.S. tax benefits of inversions. Under the temporary regulations, the former stockholders of U.S. corporations acquired by a foreign corporation within 36 months of the signing date of the last such acquisition are aggregated for the purpose of determining whether the foreign corporation will be treated as a domestic corporation for U.S. federal tax purposes because at least 80 percent of the stock of the foreign corporation is held by former stockholders of a U.S. corporation. The requirement to aggregate the stockholders in such acquisitions for the purpose of determining whether the 80 percent threshold is met may limit our ability to use our stock to acquire U.S. corporations or their assets in the future.

The U.S. Treasury and the IRS also issued proposed regulations on April 4, 2016 that address whether an interest in a related corporation is debt or equity. The proposed regulations would treat certain inter-company debt issued on or after that date as equity including, subject to certain exceptions, inter-company debt issued in certain distributions, acquisitions of related party stock and asset reorganizations. As drafted, the proposed regulations would limit the ability of our U.S. group to deduct interest on such new inter-company debt. The proposed regulations could also result in recharacterization of inter-company debt to equity for inter-company debt incurred to provide funding for an acquisition by the U.S. group if, and to the extent of, certain cash or property transfers by our U.S. group to the foreign affiliates within 36 months before or after these inter-company borrowings. These limitations could result in more of our future income being taxed by the United States and thereby increase our effective tax rate.

In July 2015, the International Tax Bipartisan Tax Working Group of the United States Senate Committee on Finance, or the Finance Committee, issued its report on international tax reform. The Finance Committee’s co-chairs concluded that it will be necessary to limit earnings stripping by foreign multinationals through interest deductions on inter-company debt in order to eliminate a competitive advantage that foreign multinationals would otherwise have over domestic multinational companies. This and other international tax reforms proposed by the Finance Committee could result in more of our income being taxed by the United States and thereby increase our effective tax rate.

In addition, the Organization for Economic Co-operation and Development released its Base Erosion and Profit Shifting project final report on October 5, 2015. This report provides the basis for international standards for corporate taxation that are designed to prevent, among other things, the artificial shifting of income to tax havens and low-tax jurisdictions, the erosion of the tax base through interest deductions on inter-company debt and the artificial avoidance of permanent establishments (i.e., tax nexus with a jurisdiction). Legislation to adopt these standards has been enacted or is currently under consideration in a number of jurisdictions. As a result, our income may be taxed in jurisdictions where it is not currently taxed and at higher rates of tax than it is currently taxed, which may substantially increase our effective tax rate.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.*

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, sales and marketing and scientific and medical personnel, including our executive committee composed of our Chairman, President and Chief Executive Officer, Timothy P. Walbert; our Executive Vice President, Chief Business Officer, Robert F. Carey; our Executive Vice President, Chief Financial Officer, Paul W. Hoelscher; our Executive Vice President, Company Secretary and Managing Director, Ireland, David G. Kelly; our Executive Vice President, Chief Operating Officer, Barry J. Moze; our Executive Vice President, Research and Development and Chief Medical Officer, Jeffrey W. Sherman, M.D., FACP; our Executive Vice President, General Counsel, Brian K. Beeler; our Executive Vice President, Rheumatology and Primary Care Business Units, George Hampton; our Executive Vice President, Global Orphan Business Unit, Dave Happel; our Senior Vice President, Commercial Operations, Timothy J. Ackerman; and our Senior Vice President, Corporate Communications, Geoffrey

M. Curtis. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide performance stock units, or PSUs, and stock options and restricted stock units that vest over time. The value to employees of PSUs, stock options and restricted stock units will be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, sales and marketing, regulatory affairs, clinical development, medical affairs and development teams may terminate their employment with us on short notice. Although we have written employment arrangements with all of our employees, these employment arrangements generally provide for at-will employment, which means that our employees can leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior sales and marketing and scientific and medical personnel.

Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize medicines and medicine candidates will be limited.

We are, with respect to our current medicines, and will be, with respect to any other medicine or medicine candidate for which we obtain FDA or EMA approval or which we acquire, subject to ongoing FDA or the EMA obligations and continued regulatory review, which may result in significant additional expense. Additionally, any other medicine candidate, if approved by the FDA or the EMA, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our medicines.*

Any regulatory approvals that we obtain for our medicine candidates may also be subject to limitations on the approved indicated uses for which the medicine may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the medicine candidate. In addition, with respect to our current FDA-approved medicines (and with respect to our medicine candidates, if approved), the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the medicine are subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, GCPs, international conference on harmonization regulations, or ICH regulations, and GLPs, which are regulations and guidelines enforced by the FDA for all of our medicines in clinical development, for any clinical trials that we conduct post-approval. In connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we assumed responsibility for completing an ongoing Pediatric Research Equity Act post-marketing requirement study in children 12 years to 16 years and 11 months of age with juvenile rheumatoid arthritis. This report was submitted to the FDA in December 2015. With respect to RAVICTI, the FDA imposed several post-marketing requirements and a post-marketing commitment, which include remaining obligations to conduct studies in UCD patients during the first two months of life and from two months to two years of age, including a study of the pharmacokinetics in both age groups, and a randomized study to determine the safety and efficacy in UCD patients who are treatment naïve to phenylbutyrate treatment. Although we are committed to carrying out these commitments, there are challenges in conducting studies in pediatric patients including availability of study sites, patients, and obtaining parental informed consent. On June 29, 2016, we submitted an sNDA with the FDA for RAVICTI to expand the age range for chronic management of UCDs from two years of age and older to two months of age and older. Subject to positive data from on-going studies, we have targeted an sNDA submission in the first quarter of 2018 in relation to UCD patients during the first two months of life. In connection with our acquisition of Crealta Holdings LLC, or Crealta, in January 2016, we assumed responsibility for an observational study related to KRYSTEXXA. Thus far in this study there have been no new safety signals and the reported safety results parallel those in the KRYSTEXXA product label. We are continuing to screen and enroll patients in the near term. With respect to QUINSAIR, we are required to conduct post-marketing clinical studies in cystic fibrosis patients pursuant to obligations in the MAA for QUINSAIR and submit data to the EMA regularly regarding observed clinical product profile and safety assessment.

In addition, the FDA closely regulates the marketing and promotion of drugs and biologics. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturers' promotional communications. A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of medicines for off-label uses and other sales practices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust

violations, violations of the Food, Drug and Cosmetic Act, false claims laws, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of medicines for unapproved uses, pricing and Medicare and/or Medicaid reimbursement.

Later discovery of previously unknown problems with a medicine, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the medicine, withdrawal of the medicine from the market, or voluntary or mandatory medicine recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of medicine license approvals;
- medicine seizure or detention, or refusal to permit the import or export of medicines; and
- injunctions, the imposition of civil or criminal penalties, or exclusion, debarment or suspension from government healthcare programs.

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

Coverage and reimbursement may not be available, or reimbursement may be available at only limited levels, for our medicines, which could make it difficult for us to sell our medicines profitably or to successfully execute planned medicine price increases.*

Market acceptance and sales of our medicines will depend in large part on global coverage and reimbursement policies and may be affected by future healthcare reform measures, both in the United States and other key international markets. Successful commercialization of our medicines will depend in part on the availability of governmental and third-party payer reimbursement for the cost of our medicines. Government health administration authorities, private health insurers and other organizations generally provide reimbursement for healthcare. In particular, in the United States, private health insurers and other third-party payers often provide reimbursement for medicines and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, the EU and other significant or potentially significant markets for our medicines and medicine candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medicines and services, particularly for new and innovative medicines and therapies, which has resulted in lower average selling prices. Further, the increased scrutiny of prescription drug pricing practices and emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on medicine pricing, reimbursement and usage, which may adversely affect our medicine sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general. These pressures may create negative reactions to any medicine price increases, or limit the amount by which we may be able to increase our medicine prices, which may adversely affect our medicine sales and results of operations.

Patients are unlikely to use our medicines unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our medicines. Third-party payers may limit coverage to specific medicines on an approved list, also known as a formulary, which might not include all of the FDA-approved medicines for a particular indication. Moreover, a third-party payer’s decision to provide coverage for a medicine does not imply that an adequate reimbursement rate will be approved. Additionally, one third-party payer’s decision to cover a particular medicine does not ensure that other payers will also provide coverage for the medicine, or will provide coverage at an adequate reimbursement rate. Even though we have contracts with some PBMs in the United States, that does not guarantee that they will perform in accordance with the contracts, nor does that preclude them from taking adverse actions against us, which could materially adversely affect our operating results. In addition, the existence of such PBM contracts does not guarantee coverage by such PBM’s contracted health plans or adequate reimbursement to their respective providers for our medicines. For example, two significant PBMs placed DUEXIS and VIMOVO on their exclusion lists beginning in 2015, which has resulted in a loss of coverage for patients whose healthcare plans have adopted these PBM lists. While DUEXIS and VIMOVO were removed from the CVS Caremark 2017 exclusion list, we cannot guarantee that CVS Caremark will not later add these medicines back to its exclusion list or that we will be able to otherwise expand formulary access for DUEXIS and VIMOVO under health plans that contract with CVS Caremark. Also, as noted above, we were recently in a contract and rebate dispute with Express Scripts involving DUEXIS, RAYOS and VIMOVO. In September 2016, we entered into a settlement agreement and mutual release with Express Scripts pursuant to which we and Express Scripts were released from any and all claims relating to the litigation without admitting any fault or wrongdoing and we agreed to pay Express Scripts $65.0 million. Additional healthcare plan formularies may also exclude our medicines from coverage due to the actions of certain PBMs, future price increases we may implement, our use of the HorizonCares program or any other co-pay programs, or other reasons. If our strategies to mitigate formulary exclusions are not effective, these events may reduce the likelihood

that physicians prescribe our medicines and increase the likelihood that prescriptions for our medicines are not filled.

Outside of the United States, the success of our medicines, including BUPHENYL, LODOTRA, PROCYSBI, QUINSAIR, RAVICTI and, following the IMUKIN Acquisition, interferon gamma-1b (currently commercialized under the trade names IMUKIN, IMUKINE, IMMUKIN and IMMUKINE), will depend largely on obtaining and maintaining government coverage, because in many countries patients are unlikely to use prescription drugs that are not covered by their government healthcare programs. To date, reimbursement for LODOTRA has been obtained in Germany, Italy, Sweden and Switzerland. Mundipharma is seeking coverage for LODOTRA in a number of countries and currently sells LODOTRA without coverage in a limited number of countries. BUPHENYL is marketed in select countries throughout Europe, the Middle East and the Asia-Pacific region. With respect to RAVICTI, we expect to begin commercializing the medicine in Europe in 2017. PROCYSBI is marketed in select countries in Europe and QUINSAIR was recently launched in certain countries in Europe, but we cannot be certain that existing reimbursement in EU countries will be maintained or that we will be able to secure reimbursement in additional countries. Negotiating coverage and reimbursement with governmental authorities can delay commercialization by 12 months or more. Coverage and reimbursement policies may adversely affect our ability to sell our medicines on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and we expect prices of prescription pharmaceuticals to decline over the life of the medicine or as volumes increase. Many countries in the EU have increased the amount of discounts required on medicines, which we believe has impacted the reimbursement rates and timing to launch for LODOTRA to date, and we expect these discounts to continue as countries attempt to manage healthcare expenditures, especially in light of current economic conditions. As a result of these pricing practices, it may become difficult to achieve or sustain profitability or expected rates of growth in revenue or results of operations. Any shortfalls in revenue could adversely affect our business, financial condition and results of operations.

In light of such policies and the uncertainty surrounding proposed regulations and changes in the coverage and reimbursement policies of governments and third-party payers, we cannot be sure that coverage and reimbursement will be available for any of our medicines in any additional markets or for any other medicine candidates that we may develop. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our medicines. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize our medicines.

We expect to experience pricing pressures in connection with the sale of our medicines due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals relating to outcomes and quality. For example, in March 2016, the Centers for Medicare & Medicaid Services, or CMS, announced a Proposed Rule that would test new payment models for Medicare Part B prescription drugs, and provider services incident to, or otherwise related to, such drugs. Generally, the Proposed Rule includes payment models that are designed on quality and value propositions and include incentives to drive utilization of efficient therapies and make payments based on clinical outcomes. The Proposed Rule greatly differs from the current reimbursement methodology for Medicare Part B drugs. The comment period for the Proposed Rule closed on May 9, 2016. Since the closing of the comment period, the Proposed Rule has been subject to significant and ongoing discussion among stakeholders including industry, payers, healthcare providers and other interested organizations. The Proposed Rule would not take effect until CMS considers the comments received and issues a Final Rule.

There may be additional pressure by payers, healthcare providers, and members of Congress, to use generic drugs that contain the active ingredients found in our medicines or any other medicine candidates that we may develop or acquire. If we fail to successfully secure and maintain coverage and adequate reimbursement for our medicines or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our medicines and expected revenue and profitability which would have a material adverse effect on our business, results of operations, financial condition and prospects.

We may also experience pressure from payers concerning certain promotional approaches that we may implement such as our HorizonCares program or any other co-pay or free medicine programs whereby we assist qualified patients with certain out-of-pocket expenditures for our medicine. If we are unsuccessful with our HorizonCares program or any other co-pay initiatives or free medicine programs, or we alternatively are unable to secure expanded formulary access through additional arrangements with PBMs or other payers, we would be at a competitive disadvantage in terms of pricing versus preferred branded and generic competitors. We may also experience financial pressure in the future which would make it difficult to support investment levels in areas such as managed care contract rebates, HorizonCares and other access tools.

We are subject to federal, state and foreign healthcare laws and regulations and implementation or changes to such healthcare laws and regulations could adversely affect our business and results of operations.*

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to regulate and to change the healthcare system in ways that could affect our ability to sell our medicines profitably. In the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs (including a number of proposals pertaining to prescription drugs, specifically), improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to civil and/or criminal penalties, damages, fines, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business.

We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved medicine. An expansion in the government's role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription medicines, lower reimbursements for providers using our medicines, reduce medicine utilization and adversely affect our business and results of operations. It is unclear whether and to what extent, if at all, other potential developments resulting from the ACA, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us with additional revenue to offset the annual excise tax (on certain medicine sales) enacted under the ACA, subject to limited exceptions. It is possible that the tax burden, if ours is not excepted, would adversely affect our financial performance, which in turn could cause the price of our ordinary shares to decline. The ACA, among other things, also established a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Further, certain hospitals and other providers, or covered entities, may access the 340B Drug Pricing Program, administered by the Health Resources and Services Administration, or HRSA, to obtain discounted prices on "covered outpatient drugs" (prescription drugs and biologics other than vaccines) from drug manufacturers. Generally, manufacturers must offer 340B discounts to these covered entities as a prerequisite to Medicaid reimbursement for the drugs. The discount amount to "patients" (as defined by HRSA) of covered entities is significant. The number of covered entities that may access the 340B prices has been growing and includes certain free-standing cancer hospitals.

Moreover, certain politicians, including presidential candidates, have announced plans to regulate the prices of medicines. The majority of our medicines are purchased by private payers, and we do not believe that any such legislation, if enacted, would have a material effect on us or our business. However, we cannot know what form any such legislation may take or the market's perception of how such legislation would affect us. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our current medicines and/or those for which we may receive regulatory approval in the future.

We are subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

In the United States, we are subject directly, or indirectly through our customers, to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, civil monetary penalty statutes prohibiting beneficiary inducements, and similar state laws, federal and state privacy and security laws, sunshine laws, government price reporting laws, and other fraud laws. These laws may impact, among other things, our current and proposed sales, marketing and educational programs, as well as other possible relationships with customers, pharmacies, physicians, payers, and patients.

Compliance with these laws, including the development of a comprehensive compliance program, is difficult, costly and time consuming. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. These risks may be increased where there are evolving interpretations of applicable regulatory requirements, such as those applicable to manufacturer co-pay initiatives. Pharmaceutical manufacturer co-pay initiatives and free medicine programs are the subject of ongoing litigation (involving other manufacturers and to which we are not a party) and evolving interpretations of applicable regulatory requirements and certain state laws, and any change in the regulatory or enforcement environment regarding such programs could impact our ability to offer such programs. If we are unsuccessful with our HorizonCares programs, any other co-pay initiatives or free medicine programs, we would be at a competitive disadvantage in terms of pricing versus preferred branded and generic competitors, or be subject to significant penalties. We are engaged in various business arrangements with current and potential customers, and we can give no assurance that such arrangements would not be subject to scrutiny under such laws, despite our efforts to properly structure such arrangements. Even if we structure our programs with the intent of compliance with such laws, there can be no certainty that we would not need to defend our business activities against enforcement or litigation. Further, we cannot give any assurances that prior business activities or arrangements of other companies that we acquire will not be scrutinized or subject to enforcement or litigation.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA, among other things, imposed new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in significant civil monetary penalties.

We are unable to predict whether we could be subject to actions under any of these or other healthcare laws, or the impact of such actions. If we are found to be in violation of, or to encourage or assist the violation by third parties of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, withdrawal of regulatory approval, imprisonment, exclusion from government healthcare reimbursement programs, contractual damages, reputational harm, diminished profits and future earnings, injunctions and other associated remedies, or private "qui tam" actions brought by individual whistleblowers in the name of the government, and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Our medicines or any other medicine candidate that we develop may cause undesirable side effects or have other properties that could delay or prevent regulatory approval or commercialization, result in medicine re-labeling or withdrawal from the market or have a significant impact on customer demand.*

Undesirable side effects caused by any medicine candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, or cause us to evaluate the future of our development programs. In our two Phase 3 clinical trials with DUEXIS, the most commonly reported treatment-emergent adverse events were nausea, dyspepsia, diarrhea, constipation and upper respiratory tract infection. In Phase 3 endoscopic registration clinical trials with VIMOVO, the most commonly reported treatment-emergent adverse events were erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain, nausea and upper respiratory tract infection. The most common side effects observed in pivotal trials for ACTIMMUNE were "flu-like" or constitutional symptoms such as fever, headache, chills, myalgia and fatigue. The most commonly reported treatment-emergent adverse events in the Phase 3 clinical trials with RAYOS/LODOTRA included flare in rheumatoid arthritis related symptoms, abdominal pain, nasopharyngitis, headache, flushing, upper respiratory tract infection, back pain and weight gain. The most common adverse events reported in a Phase 2 clinical trial of PENNSAID 2% were application site reactions, such as dryness, exfoliation, erythema, pruritus, pain, induration, rash and scabbing. With respect to BUPHENYL, the most common side effects are change in the frequency of breathing, lack of or irregular menstruation, lower back, side, or stomach pain, mood or mental changes, muscle pain or twitching, nausea or vomiting, nervousness or restlessness, swelling of the feet or lower legs, unpleasant taste and unusual tiredness or weakness. With respect to RAVICTI, the most common side effects are diarrhea, nausea, decreased appetite, gas, vomiting, high blood levels of ammonia, headache, tiredness and dizziness. With respect to KRYSTEXXA, the most commonly reported serious adverse reactions in the pivotal trial were gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis, exacerbation of pre-existing congestive heart failure and vomiting. With respect to MIGERGOT, the most commonly reported adverse reactions are ischemia, cyanosis, absence of pulse, cold extremities, gangrene, precordial distress and pain, electrocardiogram change, muscle pain, nausea and vomiting, rectal or anal ulcer, parathesias, numbness weakness, vertigo, localized edemas and itching. With respect to PROCYSBI, the most common side effects include vomiting, nausea, abdominal pain, breath odor, diarrhea, skin odor, fatigue, rash and headache. With respect to QUINSAIR, the most common side effects include itching, wheezing, hives, rash, swelling, pale skin color, fast heartbeat, and faintness.

The FDA or other regulatory authorities may also require, or we may undertake, additional clinical trials to support the safety profile of our medicines or medicine candidates.

In addition, if we or others identify undesirable side effects caused by our medicines or any other medicine candidate that we may develop that receives marketing approval, or if there is a perception that the medicine is associated with undesirable side effects:

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- regulatory authorities may withdraw their approval of the medicine or place restrictions on the way it is prescribed;
- we may be required to change the way the medicine is administered, conduct additional clinical trials or change the labeling of the medicine or implement a risk evaluation and mitigation strategy; and
- we may be subject to increased exposure to product liability and/or personal injury claims.

If any of these events occurred with respect to our medicines, our ability to generate significant revenues from the sale of these medicines would be significantly harmed.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or if they experience regulatory compliance issues, we may not be able to obtain regulatory approval for or commercialize our medicine candidates and our business could be substantially harmed.*

We have agreements with third-party contract research organizations, or CROs, to conduct our clinical programs, including those required for post-marketing commitments, and we expect to continue to rely on CROs for the completion of on-going and planned clinical trials. We may also have the need to enter into other such agreements in the future if we were to develop other medicine candidates or conduct clinical trials in additional indications for our existing medicines. In connection with our on-going Phase 3 study to evaluate ACTIMMUNE for the treatment of FA, we are working with the Clinical Trials Coordination Center, an academic research organization, or ARO, that is part of the Center for Human Experimental Therapeutics at the University of Rochester as well as collaborating with the Friedreich's Ataxia Research Alliance, or FARA, and select investigators of FARA's Collaborative Clinical Research Network in FA. In connection with the investigator-initiated study to evaluate ACTIMMUNE in combination with PD-1/PD-L1 inhibitors in various forms of cancer including advanced urothelial carcinoma (bladder cancer) and renal cell carcinoma, we are collaborating with Fox Chase Cancer Center. In connection with our ongoing study to evaluate RAYOS/LODOTRA on the fatigue experienced by systemic lupus erythematosus patients, we are collaborating with the Alliance for Lupus Research. We rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol. We, our CROs and our ARO are required to comply with current GCP or ICH regulations. The FDA enforces these GCP or ICH regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs or collaborators fail to comply with applicable GCP or ICH regulations, the data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCP or ICH regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and may require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our CROs or collaborators violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. We must also obtain certain third-party institutional review board, or IRB, and ethics committee approvals in order to conduct our clinical trials. Delays by IRBs and ethics committees in providing such approvals may delay our clinical trials.

If any of our relationships with these third-party CROs or collaborators terminate, we may not be able to enter into similar arrangements on commercially reasonable terms, or at all. If CROs or collaborators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our medicines and medicine candidates. As a result, our results of operations and the commercial prospects for our medicines and medicine candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs or collaborators can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO or collaborator commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs and collaborators, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition or prospects.

Clinical development of drugs and biologics involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.*

Clinical testing is expensive and can take many years to complete, and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of potential medicine candidates may not be predictive of the results of later-stage clinical trials. Medicine candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical testing. For example, Raptor announced on in September 2015, based on information then available, that it would not advance its program for the treatment of pediatric NASH with PROCYSBI after a Phase 2b trial failed achieve its primary endpoints.

With respect to our on-going Phase 3 clinical trial to evaluate ACTIMMUNE for the treatment of FA, and the investigator-initiated study to evaluate ACTIMMUNE in combination with OPDIVO® nivolumab in advanced solid tumors and to the extent that we are required to conduct additional clinical development of any of our existing or later acquired medicines or we conduct clinical development of earlier stage medicine candidates or for other additional indications for RAYOS/LODOTRA, we may experience delays in these clinical trials or investigator-initiated studies. We do not know whether any additional clinical trials will be initiated in the future, begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining IRB or ethics committee approval at each site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial;
- adding new sites; or
- manufacturing sufficient quantities of medicine candidates for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the medicine candidate being studied in relation to other available therapies, including any new drugs or biologics that may be approved for the indications we are investigating. Furthermore, we rely and expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our future clinical trials and while we have and intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our medicine candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our collaborators, the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a medicine candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or if we terminate, any clinical trial of our medicine candidates, the commercial prospects of our medicine candidates will be harmed, and our ability to generate medicine revenues from any of these medicine candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our medicine development and approval process and jeopardize our ability to commence medicine sales and generate revenues.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of one or more of our medicine candidates.

Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our medicine candidates.

Business interruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. While we carry insurance for certain of these events and have implemented disaster management plans and contingencies, the occurrence of any of these business interruptions could seriously harm our business and financial condition and increase our costs and expenses. We conduct significant management operations at both our global headquarters located in Dublin, Ireland and our U.S. office located in Lake Forest, Illinois. If our Dublin or Lake Forest offices were affected by a natural or man-made disaster or other business interruption, our ability to manage our domestic and foreign operations could be impaired, which could materially and adversely affect our results of operations and financial condition. We currently rely, and intend to rely in the future, on third-party manufacturers and suppliers to produce our medicines and third-party logistics partners to ship our medicines. Our ability to obtain commercial supplies of our medicines could be disrupted and our results of operations and financial condition could be materially and adversely affected if the operations of these third-party suppliers or logistics partners were affected by a man-made or natural disaster or other business interruption. The ultimate impact of such events on us, our significant suppliers and our general infrastructure is unknown.

We are dependent on information technology systems, infrastructure and data, which exposes us to data security risks.

We are dependent upon information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Our business partners face similar risks and any security breach of their systems could adversely affect our security posture. A security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, any of which could disrupt our business and/or result in increased costs or loss of revenue. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our medicines.*

We face an inherent risk of product liability claims as a result of the commercial sales of our medicines and the clinical testing of our medicine candidates. For example, we may be sued if any of our medicines or medicine candidates allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in

design, a failure to warn of dangers inherent in the medicine, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our medicines and medicine candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our medicines or medicine candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and resources;
- substantial monetary awards to trial participants or patients;
- medicine recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize our medicines or medicine candidates.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of medicines we develop. We currently carry product liability insurance covering our clinical studies and commercial medicine sales in the amount of $75 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the on-going commercialization of our current medicines in the United States, and/or the potential commercial launches of any of our medicines in additional markets or for additional indications, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our business involves the use of hazardous materials, and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our medicine candidates and other hazardous compounds. We and our manufacturers are subject to federal, state and local as well as foreign laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state, federal or foreign authorities may curtail the use of these materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage. If we are subject to any liability as a result of our third-party manufacturers' activities involving hazardous materials, our business and financial condition may be adversely affected. In the future we may seek to establish longer-term third-party manufacturing arrangements, pursuant to which we would seek to obtain contractual indemnification protection from such third-party manufacturers potentially limiting this liability exposure.

Our employees, independent contractors, principal investigators, consultants, vendors, distributors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, distributors and CROs may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by our employees and other third parties may also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective

in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment.

Risks Related to our Financial Position and Capital Requirements

In the past we have incurred significant operating losses, and we recently achieved operating profitability.*

We have a limited operating history and even less history operating as a combined organization following the acquisitions of Vidara, Hyperion, Crealta and Raptor. We have financed our operations primarily through equity and debt financings and have incurred significant operating losses in the past. We had an operating loss of $17.1 million for the nine months ended September 30, 2016, operating income of $55.4 million for the year ended December 31, 2015 and operating losses of $8.5 million and $42.9 million for the years ended December 31, 2014 and 2013, respectively. We had a net loss of $36.3 million and a net income of $39.5 million for the nine months ended September 30, 2016 and the year ended December 31, 2015, respectively, and net losses of $263.6 million and $149.0 million for the years ended December 31, 2014 and 2013, respectively. As of September 30, 2016, we had an accumulated deficit of $717.5 million. Our prior losses have resulted principally from costs incurred in our development activities for our medicines and medicine candidates, commercialization activities related to our medicines, costs associated with our acquisition transactions and costs associated with derivative liability accounting. Our prior losses, combined with possible future losses, have had and will continue to have an adverse effect on our shareholders' deficit and working capital. While we anticipate that we will continue to generate operating profits in the future, whether we can sustain this will depend on the revenues we generate from the sale of our medicines being sufficient to cover our operating expenses.

We have limited sources of revenues and significant expenses. We cannot be certain that we will sustain profitability, which would depress the market price of our ordinary shares and could cause our investors to lose all or a part of their investment.*

Our ability to sustain profitability depends upon our ability to generate sales of our medicines. We have a limited history of commercializing our medicines as a company, and commercialization has been primarily in the United States. We may never be able to successfully commercialize our medicines or develop or commercialize other medicines in the United States or in the EU, which we believe represents our most significant commercial opportunity. Our ability to generate future revenues depends heavily on our success in:

- continued commercialization of our existing medicines and any other medicine candidates for which we obtain approval;
- obtaining FDA approvals for additional indications for ACTIMMUNE and RAVICTI;
- securing additional foreign regulatory approvals for our medicines in territories where we have commercial rights; and
- developing, acquiring and commercializing a portfolio of other medicines or medicine candidates in addition to our current medicines.

Even if we do generate additional medicine sales, we may not be able to sustain profitability on a quarterly or annual basis. Our failure to remain profitable would depress the market price of our ordinary shares and could impair our ability to raise capital, expand our business, diversify our medicine offerings or continue our operations.

We may need to obtain additional financing to fund additional acquisitions.*

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- commercialize our existing medicines in the United States, including the substantial expansion of our sales force in recent years, and our planned commercial launch of RAVICTI in Europe in 2017;
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- complete the regulatory approval process, and any future required clinical development related thereto, for our medicines and medicine candidates;
- potentially acquire other businesses or additional complementary medicines or medicines that augment our current medicine portfolio, including costs associated with refinancing debt of acquired companies; and
- conduct clinical trials with respect to potential additional indications, as well as conduct post-marketing requirements and commitments, with respect to our medicines and medicines we acquire.

While we believe that our existing cash and cash equivalents will be sufficient to fund our operations based on our current expectations of continued revenue growth, we may need to raise additional funds if we choose to expand our commercialization or development efforts more rapidly than presently anticipated, if we develop or acquire additional medicines or acquire companies, or if our revenue does not meet expectations.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our medicines or medicine candidates or one or more of our other research and development initiatives, or delay, cut back or abandon our plans to grow the business through acquisition. We also could be required to:

- seek collaborators for one or more of our current or future medicine candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms our rights to technologies or medicine candidates that we would otherwise seek to develop or commercialize ourselves.

In addition, if we are unable to secure financing to support future acquisitions, our ability to execute on a key aspect of our overall growth strategy would be impaired.

Any of the above events could significantly harm our business, financial condition and prospects.

We have incurred a substantial amount of debt, which could adversely affect our business, including by restricting our ability to engage in additional transactions or incur additional indebtedness, and prevent us from meeting our debt obligations.*

As of September 30, 2016, we had $1,147.2 million book value, or $1,270.0 million principal amount, of indebtedness, including $395.0 million in secured indebtedness. In connection with the acquisition of Hyperion, we issued $475.0 million aggregate principal amount of 6.625% Senior Notes due 2023, or the 2023 Senior Notes, in April 2015 and borrowed $400.0 million in principal amount of secured loans pursuant to a credit agreement we entered into in May 2015 with Citibank, N.A., as administrative and collateral agent, and the lenders from time to time party thereto providing for (i) the six-year $400.0 million term loan facility; (ii) an uncommitted accordion facility subject to the satisfaction of certain financial and other conditions; and (iii) one or more uncommitted refinancing loan facilities with respect to loans thereunder, or the 2015 Senior Secured Credit Facility. We repaid $1.0 million in principal amount from this facility quarterly from the third quarter of 2015 to the third quarter of 2016. In connection with the acquisition of Raptor, we issued $300.0 million aggregate principal amount of 8.75% Senior Notes due 2024, or the 2024 Senior Notes, in October 2016 and borrowed $375.0 million in principal amount of secured loans, or the 2016 Incremental Loan Facility, pursuant to an amendment to our credit agreement, or as amended, the credit agreement. Accordingly, we have a significant amount of debt outstanding on a consolidated basis.

This substantial level of debt could have important consequences to our business, including, but not limited to:

- reducing the benefits we expect to receive from our recent and any future acquisition transactions;
- making it more difficult for us to satisfy our obligations;
- requiring a substantial portion of our cash flows from operations to be dedicated to the payment of principal and interest on our indebtedness, therefore reducing our ability to use our cash flows to fund acquisitions, capital expenditures, and future business opportunities;
- exposing us to the risk of increased interest rates to the extent of any future borrowings, including borrowings under our credit agreement, at variable rates of interest;
- making it more difficult for us to satisfy our obligations with respect to our indebtedness, including our outstanding notes, our credit agreement, and any failure to comply with the obligations of any of our debt instruments, including restrictive covenants and borrowing conditions, could result in an event of default under the agreements governing such indebtedness;
- increasing our vulnerability to, and reducing our flexibility to respond to, changes in our business or general adverse economic and industry conditions;
-

- limiting our ability to obtain additional financing for working capital, capital expenditures, debt service requirements, acquisitions, and general corporate or other purposes and increasing the cost of any such financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; and placing us at a competitive disadvantage as compared to our competitors, to the extent they are not as highly leveraged and who, therefore, may be able to take advantage of opportunities that our leverage may prevent us from exploiting; and
- restricting us from pursuing certain business opportunities.

95

The credit agreement and the indentures governing the 2024 Senior Notes and the 2023 Senior Notes impose, and the terms of any future indebtedness may impose, various covenants that limit our ability and/or the ability of our restricted subsidiaries' (as designated under such agreements) 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, consolidate with or merge or sell all or substantially all of our 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 us.

Our ability to obtain future financing and engage in other transactions may be restricted by these covenants. In addition, any credit ratings will impact the cost and availability of future borrowings and our cost of capital. Our ratings at any time will reflect each rating organization's then opinion of our financial strength, operating performance and ability to meet our debt obligations. There can be no assurance that we will achieve a particular rating or maintain a particular rating in the future. A reduction in our credit ratings may limit our ability to borrow at acceptable interest rates. If our credit ratings were downgraded or put on watch for a potential downgrade, we may not be able to sell additional debt securities or borrow money in the amounts, at the times or interest rates or upon the more favorable terms and conditions that might otherwise be available. Any impairment of our ability to obtain future financing on favorable terms could have an adverse effect on our ability to refinance any of our then-existing debt and may severely restrict our ability to execute on our business strategy, which includes the continued acquisition of additional medicines or businesses.

We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful.*

Our ability to make scheduled payments under or to refinance our debt obligations depends on our financial condition and operating performance, which is subject to prevailing economic, industry and competitive conditions and to certain financial, business and other factors beyond our control. Our ability to generate cash flow to meet our payment obligations under our debt may also depend on the successful implementation of our operating and growth strategies. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to pay the principal, premium, if any, and interest on our indebtedness.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or business operations, seek additional capital or restructure or refinance our indebtedness. We cannot ensure that we would be able to take any of these actions, that these actions would be successful and permit us to meet our scheduled debt service obligations or that these actions would be permitted under the terms of existing or future debt agreements, including the indentures that govern the 2024 Senior Notes and the 2023 Senior Notes and the credit agreement. In addition, any failure to make payments of interest and principal on our outstanding indebtedness on a timely basis would likely result in a reduction of our credit rating, which could harm our ability to incur additional indebtedness.

If we cannot make scheduled payments on our debt, we will be in default and, as a result:

- our debt holders could declare all outstanding principal and interest to be due and payable;
- the administrative agent and/or the lenders under the credit agreement could foreclose against the assets securing the borrowings then outstanding; and
- we could be forced into bankruptcy or liquidation, which could result in you losing your investment.

We generally have broad discretion in the use of our cash and may not use it effectively.*

Our management has broad discretion in the application of our cash, and investors will be relying on the judgment of our management regarding the use of our cash. Our management may not apply our cash in ways that ultimately increase the value of any investment in our securities. We expect to use our existing cash to fund commercialization activities for our medicines, to potentially fund additional medicine or business acquisitions, to potentially fund additional regulatory approvals of certain of our medicines, to potentially fund development, life cycle management or manufacturing activities of our medicines for other indications, to potentially fund share repurchases, and for working capital, capital expenditures and general corporate purposes. We may also invest our cash in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our shareholders. If we do not invest or apply our cash in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause the price of our ordinary shares to decline.

Our ability to use net operating loss carryforwards and certain other tax attributes may be limited.*

Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percent change (by value) in its equity ownership over a three year period), the corporation's ability to use pre-change net operating loss carryforwards and other pre-change tax attributes to offset post-change income may be limited. In September 2014, the Vidara Merger triggered an "ownership change" limitation and, as a result, we are subject to annual limits on our ability to use the net operating loss carryforwards of Horizon Pharma, Inc. and its subsidiaries. We estimate this will result in annual limits of approximately $90 million in the years from 2016 through to 2031. Furthermore, we continue to carry forward our annual limitation resulting from an ownership change date of August 2, 2012. The limitation on pre-change net operating losses incurred prior to the August 2, 2012 change date is approximately $20 million for 2016, $15 million for 2017 and $8 million in the years from 2018 through to 2028. During the second quarter of 2015, we also recognized additional net operating losses and federal and state tax credits as a result of our acquisition of Hyperion on May 7, 2015 in the amount of approximately $31 million of federal net operating losses, state operating losses of approximately $68 million (net of federal effect) and approximately $30 million of federal and state tax credits. During the three months ended September 30, 2016, we recognized an additional federal net operating loss of $19 million from Hyperion's pre-acquisition tax return which is being carried forward into our U.S. consolidated tax group. We continue to carry forward the annual limitation related to Hyperion of $50 million resulting from the last ownership change date in 2014. Further, as a result of our acquisition of Crealta in the first quarter of 2016, we have recognized an additional estimated net operating loss carryforward of approximately $4 million. This estimate of the pre-acquisition net operating loss carryforward will be finalized once the pre-acquisition tax return has been filed, which is due on March 15, 2017. The net operating loss carryforward limitation is cumulative such that any use of the carryforwards below the limitations in one year will result in a corresponding increase in the limitations for the subsequent tax year.

Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code limits the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses to offset U.S. taxable income resulting from certain transactions. Based on the limited guidance available, we expect this limitation is applicable following the Vidara Merger. As a result, it is not currently expected that we or our other U.S. affiliates will be able to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain taxable transactions following the Vidara Merger. Notwithstanding this limitation, we expect that we will be able to fully use our U.S. net operating losses prior to their expiration. As a result of this limitation, however, it may take HPI longer to use its net operating losses. Moreover, contrary to these expectations, it is possible that the limitation under Section 7874 of the Code on the utilization of U.S. tax attributes could prevent us from fully utilizing our U.S. tax attributes prior to their expiration if we do not generate sufficient taxable income.

Any limitation on our ability to use our net operating loss and tax credit carryforwards, including the carryforwards of companies that we acquire, will likely increase the taxes we would otherwise pay in future years if we were not subject to such limitations.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.*

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. While there has been some recent improvement in some of these financial metrics, there can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate again, or do not improve, it may make

any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon commercialization or development plans. There is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Additionally, the SEC has proposed new rules on U.S. domiciled money market funds due to come into effect in the fourth quarter of 2016, which may temporarily suspend redemptions or impose liquidity fees on investors withdrawing assets during volatile periods, and this may adversely affect our investment strategy and/or liquidity.

The U.K.'s referendum to leave the EU or "Brexit," has and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the U.K.'s relationship with the EU. During this period of negotiation, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. Brexit may also have a detrimental effect on our customers, distributors and suppliers, which would, in turn, adversely affect our revenues and financial condition.

At September 30, 2016, we had $549.3 million of cash and cash equivalents consisting of cash and money market funds. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since September 30, 2016, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities owned by us.

Changes in accounting rules or policies may affect our financial position and results of operations.*

GAAP and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations. In addition, our operation as an Irish company with multiple subsidiaries in different jurisdictions adds additional complexity to the application of GAAP and this complexity will be exacerbated further if we complete additional strategic transactions. Changes in the application of existing rules or guidance applicable to us or our wholly owned subsidiaries could significantly affect our consolidated financial position and results of operations.

Covenants under the indentures governing our 2024 Senior Notes and 2023 Senior Notes and the credit agreement may restrict our business and operations in many ways, and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.*

The indentures governing the 2024 Senior Notes and the 2023 Senior Notes and the credit agreement impose various covenants that limit our ability and/or our restricted subsidiaries' ability to, among other things:

- pay dividends or distributions, repurchase equity, prepay, redeem or repurchase certain debt and make certain investments;
- incur additional debt and issue certain preferred stock;
- provide guarantees in respect of obligations of other persons;
- incur liens on assets;
- engage in certain asset sales;
- merge, consolidate with or sell all or substantially all of our assets to another person;
- enter into transactions with affiliates;
- sell assets and capital stock of our subsidiaries;
- enter into agreements that restrict distributions from our subsidiaries;
- 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 us.

These covenants may:

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;
- require us to use a substantial portion of our cash flow from operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- place us at a competitive disadvantage compared to less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

If we are unable to successfully manage the limitations and decreased flexibility on our business due to our significant debt obligations, we may not be able to capitalize on strategic opportunities or grow our business to the extent we

would be able to without these limitations.

Our failure to comply with any of the covenants could result in a default under the credit agreement or the indentures governing the 2024 Senior Notes or the 2023 Senior Notes, which could permit the administrative agent or the trustee, as applicable, or permit the lenders or the holders of the 2024 Senior Notes or the 2023 Senior Notes to cause the administrative agent or the trustee, as applicable, to declare all or part of any outstanding senior secured term loans, the 2023 Senior Notes or the 2024 Senior Notes to be immediately due and payable or to exercise any remedies provided to the administrative agent or the trustee, including, in the case of the credit agreement proceeding against the collateral granted to secure our obligations under the credit agreement. An event of default under the credit agreement or the indentures governing the 2024 Senior Notes or the 2023 Senior Notes could also lead to an event of default under the terms of the other agreements and the indenture governing our 2.50% Exchangeable Senior Notes due 2022, or the Exchangeable Senior Notes. Any such event of default or any exercise of rights and remedies by our creditors could seriously harm our business.

If intangible assets that we have recorded in connection with our acquisition transactions become impaired, we could have to take significant charges against earnings.

In connection with the accounting for our various acquisition transactions, we have recorded significant amounts of intangible assets. Under GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite-lived intangible assets has been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our medicines and medicine candidates, we may not be able to compete effectively in our markets.*

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our medicines and medicine candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own may fail to result in issued patents with claims that cover our medicines in the United States or in other foreign countries. If this were to occur, early generic competition could be expected against our current medicines and other medicine candidates in development. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which prior art can invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the APIs in DUEXIS, VIMOVO and RAYOS/LODOTRA have been on the market as separate medicines for many years, it is possible that these medicines have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications. In addition, claims directed to dosing and dose adjustment may be substantially less likely to issue in light of the Supreme Court decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc., where the court held that claims directed to methods of determining whether to adjust drug dosing levels based on drug metabolite levels in the red blood cells were not patent eligible because they were directed to a law of nature. This decision may have wide-ranging implications on the validity and scope of pharmaceutical method claims.

Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated.

Patent litigation is currently pending in the United States District Court for the District of New Jersey against several companies intending to market a generic version of VIMOVO before the expiration of certain of our patents listed in

the Orange Book. These cases are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy's; (ii) Lupin; (iii) Mylan; and (iv) Actavis Pharma. The cases arise from Paragraph IV Patent Certification notice letters from each of Dr. Reddy's, Lupin, Mylan and Actavis Pharma advising each had filed an ANDA with the FDA seeking approval to market generic versions of VIMOVO before the expiration of the patents-in-suit.

On February 24, 2015, Dr. Reddy's Laboratories, Inc. filed a Petition for inter partes review, or IPR, of U.S. Patent No. 8,557,285, one of the patents in litigation in the above referenced VIMOVO cases. On October 9, 2015, the United States Patent and Trademark Office, or the U.S. PTO, denied such Petition for IPR.

On May 21, 2015, the Coalition for Affordable Drugs VII LLC, or the Coalition for Affordable Drugs, filed a Petition for IPR of U.S. Patent No. 6,926,907, one of the patents in litigation in the above referenced VIMOVO cases. On December 8, 2015, the U.S. PTO denied such Petition for IPR.

On June 5, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of U.S. Patent No. 8,858,996, or the '996 patent, one of the patents in litigation in the above referenced VIMOVO cases. On December 17, 2015, the U.S. PTO denied such Petition for IPR.

On August 7, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of U.S. Patent No. 8,852,636, one of the patents in litigation in the above referenced VIMOVO cases. On February 11, 2016, the U.S. PTO denied such Petition for IPR.

On August 12, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of U.S. Patent No. 8,945,621, or the ’621 patent, one of the patents in litigation in the above referenced VIMOVO cases. On February 22, 2016, the Patent Trial and Appeal Board, or the PTAB, issued a decision to institute the IPR. The PTAB hearing for the ’621 patent is set for November 16, 2016. The PTAB must issue a final written decision on the IPR of the ’621 patent no later than February 22, 2017.

On August 19, 2015, Lupin filed Petitions for IPR of the ‘996 patent and U.S. Patent Nos. 8,852,636 and 8,865,190, or the ’190 patent, all patents in litigation in the above referenced VIMOVO cases. On March 1, 2016, the PTAB issued decisions to institute the IPRs for the ‘996 patent and the ’190 patent. The PTAB must issue a final written decision on the IPRs of the ’996 patent and the ’190 patent no later than March 1, 2017. Also on March 1, 2016, the PTAB denied the Petition for IPR for U.S. Patent No. 8,852,636. The PTAB hearings for the ’996 and ’190 patents are both set for November 29, 2016.

Patent litigation is currently pending in the United States District Court for the District of New Jersey against several companies intending to market a generic version of PENNSAID 2% prior to the expiration of certain of our patents listed in the Orange Book. These cases are collectively known as the PENNSAID 2% cases, and involve the following sets of defendants: (i) Actavis; and (ii) Lupin. These cases arise from Paragraph IV Patent Certification notice letters from each of Actavis and Lupin advising each had filed an ANDA with the FDA seeking approval to market a generic version of PENNSAID 2% before the expiration of the patents-in-suit. The status of these cases is as set forth above.

We received from Actavis a Paragraph IV Patent Certification Notice Letter dated September 27, 2016, against Orange Book listed U.S. Patent No. 9,415,029, advising that Actavis had filed an ANDA with the FDA for a generic version of PENNSAID 2%.

We have received from Apotex three Paragraph IV Patent Certification Notice Letters dated April 1, 2016, June 30, 2016, and September 21, 2016 against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, 8,871,809, 9,066,913, 9,101,591, 9,132,110, 9,168,304, 9,168,305, 9,220,784, 9,339,551, 9,339,552 and 9,415,029, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%.

Patent litigation is currently pending in the United States District Court for the Eastern District of Texas against Par Pharmaceutical and in the United States District Court for the District of New Jersey against Lupin and against Par Pharmaceutical, who are each intending to market generic versions of RAVICTI prior to the expiration of certain of our patents listed in the Orange Book. These cases are collectively known as the RAVICTI cases, and arise from Paragraph IV Patent Certification notice letters from each of Par Pharmaceutical and Lupin advising each had filed an ANDA with the FDA seeking approval to market a generic version of RAVICTI before the expiration of the patents-in-suit.

On April 29, 2015, Par Pharmaceutical filed Petitions for IPR of U.S. Patent No. 8,404,215 and U.S. Patent No. 8,642,012, two of the patents involved in the above mentioned RAVICTI cases. On November 4, 2015, the PTAB issued decisions instituting such IPRs and on December 14, 2015, the District Court Judge Roy Payne issued a stay pending a final written decision from the PTAB with respect to such IPRs. On September 29, 2016, the PTAB found all of the claims in U.S. Patent No. 8,404,215 to be unpatentable. We are considering whether to appeal the PTAB’s decision concerning U.S. Patent No. 8,404,215 to the Federal Circuit. On November 3, 2016, the PTAB issued a final written decision holding all of the claims of U.S. Patent No. 8,404,215 patentable.

On April 1, 2016, Lupin filed a Petition for IPR of U.S. Patent No. 9,095,559, a patent currently at issue in the Lupin RAVICTI case. On September 30, 2016, the PTAB issued a decision instituting the IPR. The PTAB must issue a final written decision on the IPR no later than September 30, 2017.

We intend to vigorously defend our intellectual property rights relating to our medicines, but we cannot predict the outcome of the VIMOVO cases, the PENNSAID 2% cases, the RAVICTI cases or the IPRs. Any adverse outcome in these matters or any new generic challenges that may arise could result in one or more generic versions of our medicines being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of our medicines, and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to our medicines fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them and threaten our ability to commercialize our medicines. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our medicines or any other medicine candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third-party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

With respect to RAVICTI, the composition of matter patent we hold would have expired in the United States in February 2015 without term extension. However, Hyperion applied for a term extension of approximately four years for this patent under the Drug Price Competition and Patent Term Restoration Act. Hyperion recently received notice that the U.S. PTO has determined that the length of the extension is 1,267 days. We cannot guarantee that pending patent applications related to RAVICTI will result in additional patents or that other existing and future patents related to RAVICTI will be held valid and enforceable or will be sufficient to deter generic competition in the United States. Therefore, it is possible that upon expiration of the RAVICTI composition of matter patent, we would need to rely on forms of regulatory exclusivity, to the extent available, to protect against generic competition.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U.S. PTO has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the U.S. PTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In

addition, the ACA allows applicants seeking approval of biosimilar or interchangeable versions of biological products such as ACTIMMUNE to initiate a process for challenging some or all of the patents covering the innovator biological product used as the reference product. This process is complicated and could result in the limitation or loss of certain patent rights. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance, in a given country, of a patent to us, covering an invention, is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on us avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the U.S. PTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which our collaborators are developing medicine candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our medicine candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our medicines and/or any other medicine candidates. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our medicine candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our medicine candidates, any molecules formed during the manufacturing process or any final medicine itself, the holders of any such patents may be able to block our ability to commercialize such medicine candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable medicine candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our medicine candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing medicines, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our medicine candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our medicine candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our medicines, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, we could lose license rights that are important to our business.*

We are party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. For example, we hold an exclusive license to Vectura Group plc's, or Vectura, proprietary technology and know-how covering the delayed-release of corticosteroids relating to RAYOS/LODOTRA. If we fail

to comply with our obligations under our agreement with Vectura or our other license agreements, or if we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market medicines covered by the license, including RAYOS/ LODOTRA.

In connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we (i) received the benefit of a covenant not to sue under AstraZeneca's patent portfolio with respect to Nexium (which shall automatically become a license under such patent portfolio if and when AstraZeneca reacquires control of such patent portfolio from Merck Sharp & Dohme Corp. and certain of its affiliates), (ii) were assigned AstraZeneca's amended and restated collaboration and license agreement for the United States with Aralez, under which AstraZeneca has in-licensed exclusive rights under certain of Aralez's patents with respect to VIMOVO, and (iii) acquired AstraZeneca's co-ownership rights with Aralez with respect to certain joint patents covering VIMOVO, all for the commercialization of VIMOVO in the United States. If we fail to comply with our obligations under our agreements with AstraZeneca or if we fail to comply with our obligations under our agreements with Aralez, our rights to commercialize VIMOVO in the United States may be adversely affected or terminated by AstraZeneca or Aralez.

We also license rights to patents, know-how and trademarks for ACTIMMUNE from Genentech Inc., or Genentech, under an agreement that remains in effect for so long as we continue to commercialize and sell ACTIMMUNE. However, Genentech may terminate the agreement upon our material default, if not cured within a specified period of time. Genentech may also terminate the agreement in the event of our bankruptcy or insolvency. Upon such a termination of the agreement, all intellectual property rights conveyed to us under the agreement, including the rights to the ACTIMMUNE trademark, revert to Genentech. If we fail to comply with our obligations under this agreement, we could lose the ability to market and distribute ACTIMMUNE, which would have a material adverse effect on our business, financial condition and results of operations.

We rely on a license from Ucyclyd with respect to technology developed by Ucyclyd in connection with the manufacturing of RAVICTI. The purchase agreement under which Hyperion purchased the worldwide rights to RAVICTI contains obligations to pay Ucyclyd regulatory and sales milestone payments relating to RAVICTI, as well as royalties on the net sales of RAVICTI. On May 31, 2013, when Hyperion acquired BUPHENYL under a restated collaboration agreement with Ucyclyd, Hyperion received a license to use some of the manufacturing technology developed by Ucyclyd in connection with the manufacturing of BUPHENYL. The restated collaboration agreement also contains obligations to pay Ucyclyd regulatory and sales milestone payments, as well as royalties on net sales of BUPHENYL. If we fail to make a required payment to Ucyclyd and do not cure the failure within the required time period, Ucyclyd may be able to terminate the license to use its manufacturing technology for RAVICTI and BUPHENYL. If we lose access to the Ucyclyd manufacturing technology, we cannot guarantee that an acceptable alternative method of manufacture could be developed or acquired. Even if alternative technology could be developed or acquired, the loss of the Ucyclyd technology could still result in substantial costs and potential periods where we would not be able to market and sell RAVICTI and/or BUPHENYL. We also license intellectual property necessary for commercialization of RAVICTI from an external party. This party may be entitled to terminate the license if we breach the agreement, including failure to pay required royalties on net sales of RAVICTI, or we do not meet specified diligence obligations in our development and commercialization of RAVICTI, and we do not cure the failure within the required time period. If the license is terminated, it may be difficult or impossible for us to continue to commercialize RAVICTI, which would have a material adverse effect on our business, financial condition and results of operations.

We also hold an exclusive license to patents and technology from Duke University, or Duke, and Mountain View Pharmaceuticals, Inc., or MVP, covering KRYSTEXXA. Duke and MVP may terminate the license if we commit fraud or for our willful misconduct or illegal conduct. Duke and MVP may also terminate the license upon our material breach of the agreement, if not cured within a specified period of time, or upon written notice if we have committed two or more material breaches under the agreement. Duke and MVP may also terminate the license in the event of our bankruptcy or insolvency. If the license is terminated, it may be impossible for us to continue to commercialize KRYSTEXXA, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, we are subject to contractual obligations under our agreements with Tripex and PARI related to QUINSAIR. Under the agreement with Tripex, we are required to pursue commercially reasonable efforts to initiate, and subsequently to complete, an additional clinical trial of QUINSAIR in a non-cystic-fibrosis patient population within a specified period of time and an obligation to progress toward filing an NDA for approval of QUINSAIR in the United States in all or part of the cystic fibrosis patient population. These obligations are subject to certain exceptions due to, for example, manufacturing delays not under our control, or delays caused by the FDA. If we fail to properly exercise such efforts to initiate and complete an appropriate clinical trial, or fail to file an NDA for U.S. approval in the cystic fibrosis patient population, during the time periods specified in the asset purchase agreement, we may be subject to various claims by Tripex and parties affiliated with Tripex. In addition, if we do not spend a minimum amount on QUINSAIR development in each of the three years following our acquisition of Raptor, we may also be obligated to pre-pay a milestone payment related to initiating a clinical trial for QUINSAIR in a

non-cystic-fibrosis indication. Under the license agreement with PARI, we are required to comply with diligence milestones related to development and commercialization of QUINSAIR in the United States, to spend a specified minimum amount per year on development activities in the United States until filing of the NDA for QUINSAIR in the United States. If we do not comply with these obligations, our licenses to certain intellectual property related to QUINSAIR may become non-exclusive in the United States or could be terminated. We are also subject to contractual obligations under our license agreements with the UCSD with respect to PROCYSBI, including diligence obligations to develop PROCYSBI for the treatment of NASH and Huntington's disease, with which we currently are not in compliance. To the extent that we fail to perform the diligence obligations under the agreement, UCSD may, with respect to such indication, terminate the license or otherwise cause the license to become non-exclusive. If one or more of these licenses was terminated, we would have no further right to use of exploit the related intellectual property, which would limit our ability to develop PROCYSBI or QUINSAIR in other indications, and could impact our ability to continue commercializing PROCYSBI or QUINSAIR in their approved indications.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one of our patents, or a patent of one of our licensors, is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

There are numerous post grant review proceedings available at the U.S. PTO (including IPR, post-grant review and ex-parte reexamination) and similar proceedings in other countries of the world that could be initiated by a third-party that could potentially negatively impact our issued patents.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ordinary shares.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our medicine candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.*

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to Ownership of Our Ordinary Shares

The market price of our ordinary shares historically has been volatile and is likely to continue to be volatile, and you could lose all or part of any investment in our ordinary shares.

The trading price of our ordinary shares has been volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- our failure to successfully execute our commercialization strategy with respect to our approved medicines, particularly our commercialization of our medicines in the United States;
- actions or announcements by third-party or government payers with respect to coverage and reimbursement of our medicines;

- disputes or other developments relating to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our medicines and medicine candidates;
- unanticipated serious safety concerns related to the use of our medicines;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our business, medicines or medicine candidates, including but not limited to clinical trial requirements for approvals or tax laws;
- inability to comply with our debt covenants and to make payments as they become due;
- inability to obtain adequate commercial supply for any approved medicine or inability to do so at acceptable prices;
- developments concerning our commercial partners, including but not limited to those with our sources of manufacturing supply;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse results or delays in clinical trials;
- our failure to successfully develop and/or acquire additional medicine candidates or obtain approvals for additional indications for our existing medicine candidates;
- introduction of new medicines or services offered by us or our competitors;
- overall performance of the equity markets, including the pharmaceutical sector, and general political and economic conditions;
- failure to meet or exceed revenue and financial projections that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- inaccurate or significant adverse media coverage;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- our inability to successfully enter new markets;
- the termination of a collaboration or the inability to establish additional collaborations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our inability to maintain an adequate rate of growth;
- ineffectiveness of our internal controls or our inability to otherwise comply with financial reporting requirements;
- adverse U.S. and foreign tax exposure;
- additions or departures of key management, commercial or regulatory personnel;
- issuances of debt or equity securities;
- significant lawsuits, including patent or shareholder litigation;
- changes in the market valuations of similar companies to us;
- sales of our ordinary shares by us or our shareholders in the future;
- trading volume of our ordinary shares;
- effects of natural or man-made catastrophic events or other business interruptions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The NASDAQ Global Select Market and the stock of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may adversely affect the market price of our ordinary shares, regardless of our actual operating performance.

We have never declared or paid dividends on our share capital and we do not anticipate paying dividends in the foreseeable future.*

We have never declared or paid any cash dividends on our ordinary shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future, including due to limitations that are currently imposed by the 2015 Senior Secured Credit Facility, the 2016 Incremental Loan Facility, the 2024 Senior Notes and the 2023 Senior Notes. Any return to shareholders will therefore be limited to the increase, if any, of our ordinary share price.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives.*

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In particular, the Sarbanes-Oxley Act of 2000, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the NASDAQ Stock Market, Inc., or NASDAQ, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. These rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time-consuming and costly. These effects are exacerbated by our transition to an Irish company and the integration of numerous acquired businesses and operations into our historical business and operating structure. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will continue to decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our medicines or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain and maintain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs that we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. If we fail to comply with the continued listing requirements of NASDAQ, our ordinary shares could be delisted from The NASDAQ Global Select Market, which would adversely affect the liquidity of our ordinary shares and our ability to obtain future financing.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform annual system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our independent registered public accounting firm is also required to deliver a report on the effectiveness of our internal control over financial reporting. Our testing, or the testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 requires that we incur substantial expense and expend significant management efforts, particularly because of our Irish parent company structure and international operations. In particular, prior to the acquisition of Crealta, Crealta and its affiliated entities were not subject to the requirements of the Sarbanes-Oxley Act. We are taking measures to establish or implement an internal control environment at these entities aimed at successfully adopting the requirements of Section 404. However, it is possible that we may experience delays in implementing or be unable to implement the required internal controls over financial reporting and other disclosure controls and procedures. If we are not able to comply with the requirements of Section 404 or if we or our independent registered public accounting firm identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our ordinary shares could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act and rules adopted by the SEC and by NASDAQ, would likely result in increased costs as we respond to their requirements.

Sales of a substantial number of our ordinary shares in the public market could cause our share price to decline.

If our existing shareholders sell, or indicate an intention to sell, substantial amounts of our ordinary shares in the public market, the trading price of such ordinary shares could decline. In addition, our ordinary shares that are either subject to outstanding options or reserved for future issuance under our employee benefit plans are or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares could decline.

Certain holders of our ordinary shares are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by our affiliates. For example, we are subject to a registration rights agreement with certain former Vidara shareholders that acquired our ordinary shares in connection with our acquisition of Vidara. Pursuant to this agreement, we filed and are required to maintain a registration statement covering the resale of ordinary shares held by these shareholders and in certain circumstances, these holders can require us to participate in an underwritten public offering of their ordinary shares. Any sales of securities by these shareholders or a public announcement of such sales could have a material adverse effect on the trading price of our ordinary shares.

In addition, any conversion or exchange of our Exchangeable Senior Notes, whether pursuant to their terms or pursuant to privately negotiated transactions between the issuer and/or us and a holder of such securities, could depress the market price for our ordinary shares.

Future sales and issuances of our ordinary shares, securities convertible into our ordinary shares or rights to purchase ordinary shares or convertible securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to decline.*

Additional capital may be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities or securities convertible into or exchangeable for ordinary shares, our shareholders may experience substantial dilution. We may sell ordinary shares, and we may sell convertible or exchangeable securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell such ordinary shares, convertible or exchangeable securities or other equity securities in subsequent transactions, existing shareholders may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of ordinary shares. We also maintain equity incentive plans, including our Amended and Restated 2014 Equity Incentive Plan, 2014 Non-Employee Equity Plan and 2014 Employee Share Purchase Plan, and intend to grant additional ordinary share awards under these and future plans, which will result in additional dilution to our existing shareholders.

Irish law differs from the laws in effect in the United States and may afford less protection to holders of our securities.

It may not be possible to enforce court judgments obtained in the United States against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised that the U.S. currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

As an Irish company, we are governed by the Irish Companies Acts, which differ in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the United States.

Provisions of our articles of association could delay or prevent a takeover of us by a third-party.

Our articles of association could delay, defer or prevent a third-party from acquiring us, despite the possible benefit to our shareholders, or otherwise adversely affect the price of our ordinary shares. For example, our articles of association:

- permit our board of directors to issue one or more series of preferred shares with rights and preferences designated by our board of directors;
- impose advance notice requirements for shareholder proposals and nominations of directors to be considered at shareholder meetings;
- stagger the terms of our board of directors into three classes; and
- require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally at a meeting of shareholders to amend or repeal our articles of association.

In addition, several mandatory provisions of Irish law could prevent or delay an acquisition of us. For example, Irish law does not permit shareholders of an Irish public limited company to take action by written consent with less than unanimous consent. We are also subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in our ordinary shares in certain circumstances.

These provisions may discourage potential takeover attempts, discourage bids for our ordinary shares at a premium over the market price or adversely affect the market price of, and the voting and other rights of the holders of, our ordinary shares. These provisions could also discourage proxy contests and make it more difficult for you and our other shareholders to elect directors other than the candidates nominated by our board of directors, and could depress the market price of our ordinary shares.

A transfer of our ordinary shares may be subject to Irish stamp duty.

In certain circumstances, the transfer of shares in an Irish incorporated company will be subject to Irish stamp duty, which is a legal obligation of the buyer. This duty is currently charged at the rate of 1.0 percent of the price paid or the market value of the shares acquired, if higher. Because our ordinary shares are traded on a recognized stock exchange in the United States, an exemption from this stamp duty is available to transfers by shareholders who hold ordinary shares beneficially through brokers which in turn hold those shares through the Depositary Trust Company, or DTC, to holders who also hold through DTC. However, a transfer by or to a record holder who holds ordinary shares directly in his, her or its own name could be subject to this stamp duty. We, in our absolute discretion and insofar as the Companies Acts or any other applicable law permit, may, or may provide that one of our subsidiaries will pay Irish stamp duty arising on a transfer of our ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of ordinary shares which would otherwise be payable by the transferee is paid by us or any of our subsidiaries on behalf of the transferee, then in those circumstances, we will, on our behalf or on behalf of such subsidiary (as the case may be), be entitled to (i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those ordinary shares and (iii) claim a first and permanent lien on the ordinary shares on which stamp duty has been paid by us or such subsidiary for the amount of stamp duty paid. Our lien shall extend to all dividends paid on those ordinary shares.

Dividends paid by us may be subject to Irish dividend withholding tax.

In certain circumstances, as an Irish tax resident company, we will be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to our shareholders. Shareholders that are resident in the United States, EU countries (other than Ireland) or other countries with which Ireland has signed a tax treaty (whether the treaty has been ratified or not) generally should not be subject to Irish withholding tax so long as the shareholder has provided its broker, for onward transmission to our qualifying intermediary or other designated agent (in the case of shares held beneficially), or our or its transfer agent (in the case of shares held directly), with all the necessary documentation by the appropriate due date prior to payment of the dividend. However, some shareholders may be subject to withholding tax, which could adversely affect the price of our ordinary shares.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our ordinary shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our rating or publish inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts cease coverage of our company or fail to publish reports on our company regularly, demand for our ordinary shares could decrease, which might cause our share price and trading volume to decline.

Securities class action litigation could divert our management's attention and harm our business and could subject us to significant liabilities.*

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the equity securities of pharmaceutical companies. These broad market fluctuations may cause the market price of our ordinary shares to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. For example, following declines in our stock price, two federal securities class action lawsuits were filed in March 2016 against us and certain of our current and former officers alleging violations of the Securities Exchange Act of 1934, as amended. Subsequently, the two actions were consolidated, and plaintiff added claims under the Securities Act and named additional defendants. This consolidated class action (captioned Schaffer v. Horizon Pharma plc, et al., Case No. 1:16-cv-01763) is currently pending in the United States District Court for the Southern District of New York. Even if we are successful in defending against this or any similar claims that may be brought in the future, litigation could result in substantial costs and may be a distraction to our management, and may lead to an unfavorable outcome that could adversely impact our financial condition and prospects.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

We completed the following issuances of unregistered securities during the three months ended September 30, 2016:

- In August 2016, we issued an aggregate of 153,743 ordinary shares to Atlas Venture Fund VI, L.P. upon the cashless exercise of a warrant to purchase an aggregate of 197,457 ordinary shares.
- In August 2016, we issued an aggregate of 4,701 ordinary shares to Atlas Venture Entrepreneurs' Fund VI, L.P. upon the cashless exercise of a warrant to purchase an aggregate of 6,038 ordinary shares.
- In August 2016, we issued an aggregate of 2,815 ordinary shares to Atlas Venture Fund VI GmbH &Co. KG upon the cashless exercise of a warrant to purchase an aggregate of 3,615 ordinary shares.

ITEM 6. EXHIBITS

The exhibits listed on the Index to Exhibits following the signature page are filed as part of this Quarterly Report on Form 10-Q.

SIGNATURES

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

HORIZON PHARMA PLC

Date: November 7, 2016 By: /s/ Timothy P. Walbert
Timothy P. Walbert
Chairman, President and Chief Executive Officer

(Principal Executive Officer)

Date: November 7, 2016 By: /s/ Paul W. Hoelscher
Paul W. Hoelscher
Executive Vice President, Chief Financial Officer

(Principal Financial Officer)

INDEX TO EXHIBITS

Exhibit Number	Description of Document
2.1[(1)]	Transaction Agreement and Plan of Merger, dated March 18, 2014, by and among Horizon Pharma, Inc., Vidara Therapeutics Holdings LLC, Vidara Therapeutics International Ltd. (now known as Horizon Pharma Public Limited Company), Hamilton Holdings (USA), Inc. and Hamilton Merger Sub, Inc.[†]
2.2[(2)]	First Amendment to Transaction Agreement and Plan of Merger, dated June 12, 2014, by and between Horizon Pharma, Inc. and Vidara Therapeutics Holdings LLC.
2.3[(3)]	Agreement and Plan of Merger, dated March 29, 2015, by and among Horizon Pharma, Inc., Ghrian Acquisition Inc. and Hyperion Therapeutics, Inc.[†]
2.4[(4)*]	Agreement and Plan of Merger, dated December 10, 2015, by and among Horizon Pharma USA, Inc., HZNP Limited, Criostail LLC, Crealta Holdings LLC and the other parties thereto.[††]
2.5[(5)]	Agreement and Plan of Merger, dated September 12, 2016, by and among Horizon Pharma Public Limited Company, Misneach Corporation and Raptor Pharmaceutical Corp.[†]
3.1[(6)]	Memorandum and Articles of Association of Horizon Pharma Public Limited Company, as amended.
4.1[(7)**]	Form of Warrant issued by Horizon Pharma, Inc. pursuant to the Securities Purchase Agreement, dated February 28, 2012, by and among Horizon Pharma, Inc. and the Purchasers and Warrant Holders listed therein.
4.2[(8)**]	Form of Warrant issued by Horizon Pharma, Inc. in Public Offering of Units.
4.3[(9)]	Indenture, dated March 13, 2015, by and among Horizon Pharma Public Limited Company, Horizon Pharma Investment Limited and U.S. Bank National Association.
4.4[(9)]	Form of 2.50% Exchangeable Senior Note due 2022 (included in Exhibit 4.3).
4.5[(10)]	Indenture, dated April 29, 2015, by and between Horizon Pharma Financing Inc. and U.S. Bank National Association.
4.6[(10)]	Form of 6.625% Senior Note due 2023 (included in Exhibit 4.5).
4.7[(11)]	First Supplemental Indenture, dated May 7, 2015, by and among Horizon Pharma Public Limited Company, certain subsidiaries of Horizon Pharma Public Limited Company and U.S. Bank National Association.
4.8[(12)]	Indenture, dated October 25, 2016, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and U.S. Bank National Association, as trustee.

4.9[(12)]	Form of 8.75% Senior Note due 2024 (included in Exhibit 4.8).
10.1[*]	Fifth Amendment to Commercial Supply Agreement, effective as of August 31, 2016, by and between Horizon Pharma Ireland Limited and Bio-Technology General (Israel) Ltd.
10.2[(12)]	Amendment No. 1, dated October 25, 2016, to Credit Agreement, dated May 7, 2015, by and among Horizon Pharma, Inc., as borrower, Horizon Pharma Public Limited Company, as Irish Holdco and a guarantor, the subsidiary guarantors party thereto, as subsidiary guarantors, the lenders party thereto and Citibank, N.A., as administrative agent and collateral agent.
10.3[*]	Amended and Restated License Agreement, effective October 30, 2012, by and between The Regents of the University of California and Horizon Orphan LLC (as successor in interest to Raptor Therapeutics Inc.), as amended March 1, 2013 and December 16, 2013.
10.4[*]	API Supply Agreement, dated November 3, 2010, by and among Cambrex Profarmaco Milano, Horizon Orphan LLC (as successor in interest to Raptor Therapeutics Inc.) and Horizon Pharma Europe B.V. (as successor in interest to Raptor Pharmaceuticals Europe B.V.), as amended April 9, 2013.
10.5[*]	Manufacturing Services Agreement, dated November 15, 2010, by and among Patheon Pharmaceuticals Inc., Horizon Orphan LLC (as successor in interest to Raptor Therapeutics Inc.) and Horizon Pharma Europe B.V. (as successor in interest to Raptor Pharmaceuticals Europe B.V.), as amended April 5, 2012 and June 21, 2013.
10.6[*]	Confidential Settlement Agreement and Mutual Release, dated September 26, 2016, by and between Horizon Pharma USA, Inc. and Express Scripts, Inc.
10.7[(+)]	Executive Employment Agreement, effective as of October 25, 2016, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and David A. Happel.

Exhibit Number	Description of Document
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

† Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Horizon Pharma Public Limited Company undertakes to furnish supplemental copies of any of the omitted schedules upon request by the Securities and Exchange Commission.

‡ Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Horizon Pharma Public Limited Company undertakes to furnish supplemental copies of any of the omitted schedules upon request by the Securities and Exchange Commission; provided, however, that Horizon Pharma Public Limited Company may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedule so furnished.

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

** Indicates an instrument, agreement or compensatory arrangement or plan assumed by Horizon Pharma Public Limited Company in the merger transaction with Vidara Therapeutics International Public Limited Company and no longer binding on Horizon Pharma, Inc.

(1) Incorporated by reference to Horizon Pharma, Inc.'s Current Report on Form 8-K, filed on March 20, 2014.

(2) Incorporated by reference to Horizon Pharma, Inc.'s Current Report on Form 8-K, filed on June 18, 2014.

(3) Incorporated by reference to Horizon Pharma Public Limited Company's Amendment No. 1 to Current Report on Form 8-K, filed on April 9, 2015.

(4)

Incorporated by reference to Horizon Pharma Public Limited Company's Annual Report on Form 10-K, filed on February 29, 2016.

(5) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on September 12, 2016.

(6) Incorporated by reference to Horizon Pharma Public Limited Company's Registration Statement on Form S-8, filed on May 4, 2016.

(7) Incorporated by reference to Horizon Pharma, Inc.'s Current Report on Form 8-K, filed on March 1, 2012.

(8) Incorporated by reference to Horizon Pharma, Inc.'s Current Report on Form 8-K, filed on September 20, 2012.

(9) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on March 13, 2015.

(10) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on April 29, 2015.

(11) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on May 11, 2015.

(12) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on October 25, 2016.