Horizon Pharma plc
Form 10-Q
November 06, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(MARK ONE)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015

OR

o 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 of incorporation or organization)	Not Applicable (I.R.S. Employer Identification No.)
Connaught House, 1st Floor 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland (Address of principal executive offices)	Not Applicable (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 x No o

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 x No o

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 x	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

Number of registrant's ordinary shares, nominal value $0.0001, outstanding as of November 2, 2015:159,293,170.

HORIZON PHARMA PLC

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

HORIZON PHARMA PLC

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share data)

	As of September 30, 2015	As of December 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 684,286	$218,807
Restricted cash	860	738
Accounts receivable, net	221,091	73,915
Inventories, net	17,729	16,865
Prepaid expenses and other current assets	16,466	14,370
Deferred tax assets, net	13,196	1,530
Total current assets	953,628	326,225
Property and equipment, net	10,380	7,241
Developed technology, net	1,650,553	696,963
In-process research and development	66,000	66,000
Other intangible assets, net	7,263	7,870
Goodwill	259,167	—
Long-term investments	42,413	—
Deferred tax assets, net, non-current	—	18,761
Other assets	9,514	11,564
TOTAL ASSETS	$ 2,998,918	$1,134,624
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Convertible debt, net	$ —	$48,334
Long-term debt—current portion	4,000	—
Accounts payable	62,083	21,011
Accrued expenses	84,364	46,625
Accrued trade discounts and rebates	124,378	76,115
Accrued royalties—current portion	45,411	25,325
Deferred revenues—current portion	1,353	1,261

Deferred tax liabilities, net	—	721
Total current liabilities	321,589	219,392
LONG-TERM LIABILITIES:		
Exchangeable notes, net	$ 278,990	$—
Long-term debt, net, net of current	858,021	297,169
Accrued royalties, net of current	125,272	48,887
Deferred revenues, net of current	9,570	8,144
Deferred tax liabilities, net, non-current	142,702	19,570
Other long-term liabilities	4,436	1,258
Total long-term liabilities	1,418,991	375,028
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares, $0.0001 nominal value; 300,000,000 shares authorized; 159,651,736 and 124,425,853 shares issued at September 30, 2015 and December 31, 2014, respectively, and 159,267,370 and 124,041,487 shares outstanding at September 30, 2015 and December 31, 2014, respectively	16	13
Treasury stock, 384,366 ordinary shares at September 30, 2015 and December 31, 2014	(4,585)	(4,585)
Additional paid-in capital	2,000,292	1,269,858
Accumulated other comprehensive loss	(32,204)	(4,363)
Accumulated deficit	(705,181)	(720,719)
Total shareholders' equity	1,258,338	540,204
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 2,998,918	$1,134,624

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

HORIZON PHARMA PLC

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(UNAUDITED)

(In thousands, except share and per share data)

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
REVENUES:				
Net sales	$226,544	$75,126	$512,506	$193,114
Cost of goods sold	61,250	13,644	151,929	46,073
Gross profit	165,294	61,482	360,577	147,041
OPERATING EXPENSES:				
Research and development	13,073	4,223	28,176	10,601
Sales and marketing	51,973	31,111	157,092	86,932
General and administrative	54,516	38,109	157,986	66,982
Total operating expenses	119,562	73,443	343,254	164,515
Operating income (loss)	45,732	(11,961)	17,323	(17,474)
OTHER (EXPENSE) INCOME NET:				
Interest expense, net	(20,300)	(5,194)	(49,780)	(13,608)
Foreign exchange loss	(86)	(2,754)	(1,010)	(3,076)
Bargain purchase gain	—	22,171	—	22,171
Loss on derivative fair value	—	—	—	(214,995)
Loss on induced conversion of debt and debt extinguishment	—	—	(77,624)	—
Other expense, net	(90)	(3,241)	(10,159)	(8,241)
Total other (expense) income, net	(20,476)	10,982	(138,573)	(217,749)
Profit (loss) before expense (benefit) for income taxes	25,256	(979)	(121,250)	(235,223)
EXPENSE (BENEFIT) FOR INCOME TAXES	21,979	(3,042)	(136,788)	(3,267)
NET INCOME (LOSS)	$3,277	$2,063	$15,538	$(231,956)
NET INCOME (LOSS) PER ORDINARY SHARE—Basic	$0.02	$0.03	$0.11	$(3.17)
WEIGHTED AVERAGE ORDINARY SHARES OUTSTANDING—Basic	159,035,580	78,392,971	145,208,252	73,109,603
NET INCOME (LOSS) PER ORDINARY SHARE—Diluted	$0.02	$0.02	$0.10	$(3.17)
WEIGHTED AVERAGE ORDINARY SHARES OUTSTANDING—Diluted	166,830,800	85,687,267	154,005,671	73,109,603
OTHER COMPREHENSIVE (LOSS) INCOME,				

NET OF TAX				
Foreign currency translation adjustments	(48)	(654)	1,559	(793)
Unrealized loss on long-term investment	(29,400)	—	(29,400)	—
Accumulated other comprehensive loss	(29,448)	(654)	(27,841)	(793)
COMPREHENSIVE INCOME (LOSS)	$(26,171)	$1,409	$(12,303)	$(232,749)

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,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 15,538	$ (231,956)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization expense	94,025	17,662
Share-based compensation	56,253	10,111
Royalty accretion	13,571	5,617
Royalty liability remeasurement	14,277	13,033
Bargain purchase gain	—	(22,171)
Loss on derivative revaluation	—	214,995
Loss on induced conversions of debt and debt extinguishment	21,581	—
Amortization of debt discount and deferred financing costs	13,328	7,087
Foreign exchange loss	1,010	3,076
Other	127	11
Changes in operating assets and liabilities:		
Accounts receivable	(135,370)	(52,033)
Inventories	12,819	129
Prepaid expenses and other current assets	417	(2,091)
Accounts payable	38,213	10,555
Accrued trade discounts and rebates	35,136	46,113
Accrued expenses and royalties	11,052	796
Deferred revenues	2,143	(324)
Deferred income taxes	(134,014)	(3,278)
Payment of original issue discount upon repayment of 2014 Term Loan Facility	(3,000)	—
Other non-current assets and liabilities	2,122	138
Net cash provided by operating activities	59,228	17,470
CASH FLOWS FROM INVESTING ACTIVITIES:		
Payments for acquisitions, net of cash acquired	(1,022,361)	(179,220)
Proceeds from liquidation of available-for-sale investments	64,623	—
Purchases of long-term investments	(71,813)	—
Purchases of property and equipment	(4,514)	(1,837)
Change in restricted cash	(122)	—
Net cash used in investing activities	(1,034,187)	(181,057)
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	(1,000)	
Net proceeds from issuance of ordinary shares	475,627	—
Proceeds from the settlement of capped call transactions	—	9,385
Proceeds from the issuance of ordinary shares in connection with warrant exercises	18,124	33,262
Proceeds from the issuance of ordinary shares through ESPP programs	1,541	649
Proceeds from the issuance of ordinary shares through stock option exercises	4,602	1,704
Payment of employee withholding taxes relating to share-based awards	(2,334)	—
Net proceeds from the 2014 Term Loan Facility	—	286,966
Net cash provided by financing activities	1,440,587	331,966
Effect of foreign exchange rate changes on cash	(149)	(78)
NET INCREASE IN CASH AND CASH EQUIVALENTS	465,479	168,301
CASH AND CASH EQUIVALENTS, beginning of the period	218,807	80,480
CASH AND CASH EQUIVALENTS, end of the period	$ 684,286	$ 248,781
Supplemental cash flow information:		
Cash paid for interest	$ 21,417	$ 3,604
Cash paid for income taxes	$ 1,903	$ 29
Fees paid for debt commitment	$ 9,000	$ 8,222
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	$ —
Goodwill and other intangible assets acquired in acquisition	$ 1,303,765	$ —
Contingent liabilities assumed in acquisition	$ 89,800	$ —

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

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 ("New Horizon" or the "Company"). Upon the consummation of the Vidara Merger, the historical financial statements of HPI became the Company's historical financial statements. Accordingly, the historical financial statements of HPI are included in the comparative prior periods.

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 the completion of the acquisition, Hyperion became a wholly-owned subsidiary of the Company and was renamed as Horizon Therapeutics, Inc. The unaudited condensed consolidated financial statements presented herein include the results of operations of the acquired business from the date of acquisition.

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, consisting only of normal recurring adjustments, considered necessary for a fair statement of the financial statements have been included. Operating results for the nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. The December 31, 2014 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by GAAP.

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 seven medicines through its orphan, primary care and specialty business units. The Company's U.S. marketed products are ACTIMMUNE® (interferon gamma-1b), BUPHENYL® (sodium phenylbutyrate) Tablets and Powder, DUEXIS® (ibuprofen/famotidine), PENNSAID® (diclofenac sodium topical solution) 2% w/w ("PENNSAID 2%"), 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 the U.S. rights to ACTIMMUNE as a result of the Vidara Merger, acquired the U.S. rights to PENNSAID 2% from Nuvo Research Inc. ("Nuvo") in October 2014, and acquired RAVICTI and BUPHENYL, known as AMMONAPS® in Europe, as a result of the acquisition of Hyperion in May 2015. The Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") adopted a positive opinion at its plenary monthly meeting in September 2015 recommending a centralized marketing authorization for RAVICTI for use as an adjunctive therapy for chronic management of adult and pediatric patients greater than two months of age with urea cycle disorders ("UCDs"). The adopted positive opinion will be considered by the European Commission for a binding decision to be issued for the granting of a centralized marketing authorization, expected to be received within 60 to 90 days from the date of adoption of the opinion.

The Company markets its products in the United States through a combined field sales force of approximately 402 representatives. The Company's strategy is to utilize the commercial strength and infrastructure the Company has established in creating a fully-integrated global biopharmaceutical company to continue the successful commercialization of its existing product portfolio while expanding and leveraging these capabilities further through the acquisition of additional biopharmaceutical products and companies.

The Company's products are distributed by retail and specialty pharmacies. A key part of the Company's commercial strategy for its primary care and specialty business units is to offer physicians the opportunity to have their patients fill prescriptions through pharmacies who participate in the Prescriptions Made Easy ("PME") program. This program is not involved in the prescribing of medicines, and is solely to assist in ensuring that when a physician determines one of the Company's medicines offers a potential clinical benefit to their patient and they prescribe one for an eligible patient, financial assistance may be available to reduce the patient's out-of-pocket costs. In the first nine months of 2015, this resulted in 96 percent of commercial patients having co-pay amounts of $10 or less when filling prescriptions for the Company's products through PME. In addition, the aggregate commercial value of the Company's patient support programs for the nine months ended September 30, 2015 was approximately $670 million. All pharmacies that fill prescriptions for the Company's medicines are fully independent, including those that participate in the PME program, the Company does not own or possess any option to purchase an ownership stake in any pharmacy that distributes its products, and the Company's relationship with each pharmacy is non-exclusive and arm's length. All of the Company's sales are processed through pharmacies independent of the Company.

The Company has a compliance program in place to address adherence with various laws and regulations relating to its sales, marketing, and manufacturing of its products, 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 PME program, to confirm their activities, adjudication and practices are consistent with the Company's compliance policies and guidance.

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

Unless otherwise indicated or the context otherwise requires, references to the "Company", "New Horizon", "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 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.

On July 7, 2015, the Company announced a proposal to acquire all of the outstanding shares of common stock of Depomed, Inc. ("Depomed") for $29.25 per share in an all-stock transaction valued at approximately $3.0 billion. Subsequently, on July 21, 2015, the Company increased the value of its all-stock proposal to acquire all of the outstanding shares of common stock of Depomed to $33.00 per share, contingent on Depomed entering into good faith discussions regarding a transaction. On August 13, 2015, the Company reiterated its proposal to acquire Depomed and fixed the exchange ratio of such offer based at 0.95 ordinary shares of the Company for each share of Depomed common stock based on the 15-day volume weighted average price of an ordinary share of the Company as of August 12, 2015.

On September 8, 2015, the Company commenced an exchange offer for all outstanding shares of Depomed common stock. Under the terms of the offer, tendering Depomed shareholders would be able to exchange each share of Depomed common stock for 0.95 ordinary shares of the Company. The exchange offer is subject to certain conditions set forth including the redemption or removal of certain poison pill rights that the Depomed board has the unilateral ability to remove, the tender of a majority of the total number of outstanding Depomed shares on a fully diluted basis, expiration or termination of the waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act") and other applicable antitrust laws and regulations, and the affirmative vote at an extraordinary general meeting of the shareholders of the Company to approve the issuance of the Company's ordinary shares in the acquisition. If the exchange offer is completed, the Company would expect to complete a second-step merger as soon as practicable thereafter in order to acquire the remaining Depomed shares. Based on publicly available information,

the Company believes that only clearance under the HSR Act is required and the waiting period under the HSR Act expired effective October 9, 2015.

In addition to the exchange offer, on September 8, 2015, the Company filed a definitive solicitation statement seeking the support of Depomed shareholders to call two related special meetings to consider and vote on proposals to remove and replace the current Depomed board of directors and to amend the Depomed bylaws to facilitate shareholder action.

On October 15, 2015, the Company filed a definitive proxy statement in connection with an extraordinary general meeting of the Company's shareholders scheduled for November 13, 2015. The principal purpose of this meeting is to approve the issuance of the Company's ordinary shares in connection with the proposed acquisition of Depomed.

On October 26, 2015, the Company extended the expiration of its exchange offer to acquire all of the outstanding shares of common stock of Depomed to November 20, 2015.

From July 9, 2015 through August 24, 2015, the Company purchased 2,250,000 shares of Depomed common stock, representing approximately 3.75% of the outstanding shares of Depomed's common stock. The shares were acquired at a cost of approximately $71.8 million and are presented as long-term investments in the condensed consolidated balance sheets. Unrealized losses of $29.4 million have been recorded in accumulated other comprehensive loss relating to this investment in the three and nine months ended September 30, 2015.

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 a new standard 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. On July 9, 2015, the FASB agreed to delay the effective date by one year. In accordance with the agreed upon delay, the new standard is effective for the Company beginning in the first quarter of 2018. Early adoption is permitted, but not before the original effective date of the standard. 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. The Company has not yet selected a transition method nor has it determined the impact of the new standard on its condensed consolidated financial statements.

In August 2014, the FASB issued Accounting Standards Update ("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 is currently in the process of evaluating the impact of adoption of ASU No. 2014-15 to its condensed consolidated financial statements and related disclosures.

On April 7, 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. The amendments in this ASU are effective for the financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within the fiscal years beginning after December 15, 2016. Early adoption is permitted for financial statements that have not been previously issued. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2015-03 to its condensed 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 is currently in the process of evaluating the impact of adoption of ASU No. 2015-11 to its condensed 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. Earlier application is permitted for financial statements that have not been previously issued. The Company is currently in the process of evaluating the impact of adoption of ASC 805 to its condensed consolidated financial statements and related disclosures.

NOTE 2 – NET INCOME (LOSS) PER SHARE

The following table presents basic net income (loss) per share for the three and nine months ended September 30, 2015 and 2014 (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Basic net income (loss) per share calculation:				
Net income (loss)	3,277	2,063	15,538	(231,956)
Weighted average of ordinary shares outstanding	159,035,580	78,392,971	145,208,252	73,109,603
Basic net income (loss) per share	$0.02	$0.03	$0.11	$(3.17)

The following table presents diluted net income (loss) per share for the three and nine months ended September 30, 2015 and 2014 (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Diluted net income (loss) per share calculation:				
Net income (loss)	3,277	2,063	15,538	(231,956)
Weighted average of ordinary shares outstanding	166,830,800	85,687,267	154,005,671	73,109,603
Diluted net income (loss) per share	$0.02	$0.02	$0.10	$(3.17)

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of ordinary shares outstanding during the period. Diluted earnings per share ("EPS") reflects the potential dilution beyond shares for basic EPS 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 our earnings.

The outstanding securities in the table below were excluded from the computation of diluted net income (loss) per share for the three and nine months ended September 30, 2015 and 2014 due to being potentially anti-dilutive:

	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Stock options	—	—	—	6,718,287
Restricted stock units	—	—	—	1,637,399
Warrants	—	—	—	7,825,821
Convertible Senior Notes	—	27,964,200	—	27,964,200
	—	27,964,200	—	44,145,707

The potentially dilutive impact of the Horizon Pharma Investment Limited ("Horizon Investment"), a wholly-owned subsidiary of the Company, March 2015 private placement of $400.0 million aggregate principal amount of 2.50% Exchangeable Senior Notes due 2022 (the "Exchangeable Senior Notes") 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 Note's principal and interest in cash. Instead, the Company is required to increase the diluted EPS denominator by the variable number of shares that would be issued upon conversion if it settled the conversion spread obligation with shares. For diluted EPS 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 was 1,298,616 and 775,807 ordinary shares for the three and nine months ended September 30, 2015, respectively.

NOTE 3 – BUSINESS ACQUISITIONS

Hyperion Acquisition

On March 29, 2015, the Company, Ghrian Acquisition Inc. ("Purchaser"), a Delaware corporation and a wholly-owned subsidiary of the Company, and Hyperion entered into a definitive Agreement and Plan of Merger providing for the acquisition by the Company of all the issued and outstanding shares of Hyperion's common stock for $46.00 per share. The acquisition was completed on May 7, 2015. The acquisition added two important medicines, RAVICTI and BUPHENYL, which increased the product portfolio of the Company from five to seven. 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):

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 month periods ended September 30, 2015, the Company incurred $4.6 million and $52.4 million, respectively, in Hyperion acquisition-related costs including, advisory, legal, accounting, valuation, severance, retention bonuses, and other professional and consulting fees. Acquisition-related costs were expensed as "General and administrative", "Research and development" and "Other, net" in the Condensed Consolidated Statement of Comprehensive Income.

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 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 quarter ended September 30, 2015, the Company recorded measurement period adjustments related to deferred tax liabilities, other liabilities, accounts receivable and inventory, which resulted in a net reduction in goodwill of $0.4 million. The measurement period adjustments were the result of the alignment of Hyperion revenue recognition policies to those of the Company.

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
Deferred tax liability	$(399,189)	$ 164	$(399,025)
Other liabilities	(502)	502	—
Accounts payable	(2,439)		(2,439)
Accrued expenses	(20,745)		(20,745)
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	11,683	175	11,858
Inventory	13,941	(443)	13,498
Prepaid expenses and other current assets	2,533		2,533
Property and equipment	1,044		1,044
Deferred tax assets	134,324		134,324
Other non-current assets	123		123
Developed technology	1,044,200		1,044,200
Goodwill	259,565	(398)	259,167
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. 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. 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. In the second and third quarters of 2015, the Company amortized $3.4 million and $4.1 million, respectively, of RAVICTI and BUPHENYL inventory step up. Finished goods at September 30, 2015 included $0.6 million and $0.6 million of stepped up RAVICTI inventory and BUPHENYL inventory, respectively. The remaining step up is anticipated to be amortized in the fourth quarter of 2015.

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 preliminary fair values of the developed technology and contingent royalties represent preliminary valuations performed with 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 products, 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 products. 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 preliminary fair value to a contingent liability for royalties potentially payable under previously existing royalty and licensing agreements related to RAVICTI and BUPHENYL. The royalties are payable under the terms of license agreements with Ucyclyd Pharma, Inc. (“Ucyclyd”) and Brusilow Enterprises LLC (“Brusilow”). See Note 14 for details of the percentages payable under such license agreements. The initial fair value of this liability of $86.8 million 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 estimated liability for royalties will be increased over time to reflect the change in its present value and accretion expense will be recorded as part of cost of goods sold.

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, ("ASC 740") 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 preliminary acquisition consideration over the estimated fair values of net assets acquired and was recorded in the condensed consolidated balance sheet as of the acquisition date.

PENNSAID 2% Acquisition

On October 17, 2014, the Company acquired the U.S. rights to PENNSAID 2% from Nuvo for $45.0 million in cash. PENNSAID 2% is approved in the United States for the treatment of the pain of osteoarthritis of the knee. The Company began marketing PENNSAID 2% in January 2015, and as such no sales or cost of goods sold were recognized in 2014.

As part of the acquisition, the Company entered into an eight-year exclusive supply agreement with Nuvo to manufacture and supply PENNSAID 2% to the Company. The initial term of the supply agreement is through December 31, 2022, 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.

Pursuant to ASC 805, the Company accounted for the acquisition of the U.S. rights to PENNSAID 2% under the acquisition method of accounting, in which the Company recognized and accounted for the acquisition of the U.S. rights to PENNSAID 2% as a business combination. Using this methodology, the Company allocated the entire purchase price of $45.0 million to a developed technology intangible asset. The valuation of the developed technology intangible asset was based on management's estimates, forecasted financial information and reasonable and supportable assumptions. The allocation was generally based on the Company's estimated fair value of the rights to payments with respect to U.S. revenue associated with PENNSAID 2% which were acquired in the transaction. This estimated fair value was determined using the income approach under the discounted cash flow method. Significant assumptions used in valuing the developed technology intangible asset included revenue projections through 2021 based on assumptions relating to pricing and reimbursement rates, market size and market penetration rates and cost

of goods sold based on current manufacturing experience, general and administrative expenses, sales and marketing expenses, and research and development expenses for clinical and regulatory support. The calculated value of the PENNSAID 2% developed technology intangible asset is amortized using the straight-line method over an estimated useful life of six years, which is the period in which the majority of the benefits from such developed technology will be recognized.

Vidara Acquisition

On March 18, 2014, HPI, Vidara Therapeutics Holdings LLC, a Delaware limited liability company ("Vidara Holdings"), Vidara, Hamilton Holdings (USA), Inc., a Delaware corporation and an indirect wholly-owned subsidiary of Vidara ("U.S. HoldCo") and Hamilton Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of U.S. HoldCo ("Merger Sub"), entered into a Transaction Agreement and Plan of Merger (the "Merger Agreement"). The Merger Agreement provided for the merger of Merger Sub with and into HPI, with HPI continuing as the surviving corporation and as a wholly-owned, indirect subsidiary of Vidara, with Vidara converting to a public limited company and changing its name to Horizon Pharma plc.

At the effective time of the Vidara Merger on September 19, 2014 (the "Effective Time"), (i) each share of HPI's common stock issued and outstanding was converted into one ordinary share of New Horizon; (ii) each equity plan of HPI was assumed by New Horizon and each outstanding option under HPI's equity plans was converted into an option to acquire the number of ordinary shares of New Horizon equal to the number of common stock underlying such option immediately prior to the Effective Time at the same exercise price per share as such option of HPI, and each other stock award that was outstanding under HPI's equity plans was converted into a right to receive, on substantially the same terms and conditions as were applicable to such equity award before the Effective Time, the number of ordinary shares of New Horizon equal to the number of shares of HPI's common stock subject to such stock award immediately prior to the Effective Time; (iii) each warrant to acquire HPI's common stock outstanding immediately prior to the Effective Time and not terminated as of the Effective Time was converted into a warrant to acquire, on substantially the same terms and conditions as were applicable under such warrant before the Effective Time, the number of ordinary shares of New Horizon equal to the number of shares of HPI's common stock underlying such warrant immediately prior to the Effective Time; and (iv) the 5.00% Convertible Senior Notes due 2018 (the "Convertible Senior Notes") of HPI remained outstanding and, pursuant to a supplemental indenture entered into effective as of the Effective Time, became convertible into the same number of ordinary shares of New Horizon at the same conversion rate in effect immediately prior to the Effective Time. Vidara Holdings retained ownership of 31,350,000 ordinary shares of New Horizon at the Effective Time. Upon consummation of the Vidara Merger (the "Closing"), the security holders of HPI (excluding the holders of HPI's Convertible Senior Notes) owned approximately 74% of New Horizon and Vidara Holdings owned approximately 26% of New Horizon. At the Closing, New Horizon made a cash payment of $210.9 million to Vidara Holdings and $2.7 million to Citibank N.A. as escrow agent under an escrow agreement associated with the Vidara Merger.

The total consideration for the acquisition of Vidara was $601.4 million, representing the $387.8 million market value of the 31,350,000 New Horizon ordinary shares that were held by prior Vidara shareholders immediately following the Closing plus the cash consideration of $213.6 million. The value of the New Horizon ordinary shares of $387.8 million was based on the September 18, 2014 closing stock price of HPI common stock of $12.37, the last closing price prior to the Effective Time.

Pursuant to ASC 805, the Company accounted for the Vidara Merger as a reverse acquisition under the acquisition method of accounting, with HPI treated as the acquiring company for accounting purposes. Identifiable assets and liabilities of Vidara, including identifiable intangible assets, were recorded based on their estimated fair values as of the date of the Closing. The excess of the fair value of the net assets acquired over the value of consideration was recorded as a bargain purchase gain. The following table summarizes the fair values assigned to the assets acquired and the liabilities assumed by the Company pursuant to the Vidara Merger, along with the resulting bargain purchase gain (in thousands):

	Allocation
Cash and cash equivalents	$ 34,401
Accounts receivable, net	11,838
Inventories	15,422
Other receivable—net working capital adjustment	195
Prepaid expenses	138
Property and equipment	289
Deferred tax assets	2,907
Customer relationships	8,100
In-process research and development	66,000
Developed technology	560,000
Accounts payable	(1,781)
Accrued expenses and other current liabilities	(32,372)

Contingent royalties	(33,600)
Other liabilities	(775)
Deferred tax liabilities	(7,170)
Bargain purchase gain	(22,171)
Fair value of consideration paid	$601,421

The fair value of the developed technology, in-process research and development ("IPR&D"), customer relationships and contingent royalties, along with any associated deferred tax assets or liabilities, represent final valuations performed with assistance by an independent appraisal firm.

Inventories acquired included raw materials and finished goods. Fair value of finished goods was determined based on the estimated selling price, net of selling costs and a margin on the selling costs. Fair value of raw materials was estimated to equal the replacement cost. A step up in the value of inventory of $14.2 million was recorded in connection with the Vidara Merger. In the first quarter of 2015, the Company recognized the remaining $3.2 million of ACTIMMUNE inventory step up in its condensed consolidated statement of comprehensive income.

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

Identifiable intangible assets and liabilities acquired included developed technology, IPR&D and customer relationships. The fair value of intangible assets is based on management's estimates, forecasted financial information and reasonable and supportable assumptions. Estimated useful lives are based on the time periods during which the intangibles are expected to result in incremental cash flows.

Developed technology intangible assets reflect the estimated value of Vidara's rights to the marketed ACTIMMUNE product as of the acquisition date. 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 sales projections and estimated direct costs for ACTIMMUNE. Indications of value are developed by discounting these benefits to their present value at a discount rate of 15% that reflects the return requirements of the market. The fair value of developed technology was recorded as an intangible asset as of the acquisition date and subsequently amortized over an estimated remaining life of 13 years.

IPR&D is related to one research and development project for the application of ACTIMMUNE in the treatment of Friedreich's ataxia ("FA"), which was incomplete at the time of the Vidara Merger. IPR&D is considered separable from the business as the project could be sold to a third-party. The fair value of IPR&D 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 sales projections and estimated direct costs. Indications of value are developed by discounting these benefits to their present value at a discount rate of 33% that reflects the return requirements of the market. The fair value of the IPR&D was recorded as an indefinite-lived intangible asset and will be tested for impairment until completion or abandonment of research and development efforts associated with the project.

Customer relationships intangible assets reflect the estimated value of Vidara's customer base for ACTIMMUNE. Vidara's customers as of the acquisition date were predominantly a small group of retail pharmacies with demand for ACTIMMUNE. As such, a significant portion of revenue growth was expected to be generated from existing customers as of the acquisition date. Management assessed the historical customer trends to identify the anticipated attrition. The fair value of customer relationships was recorded as an intangible asset as of the acquisition date and is subsequently being amortized over an estimated remaining life of 10 years.

The Company has assigned a fair value to a contingent liability for royalties potentially payable under previously existing royalty and licensing agreements related to ACTIMMUNE. The royalties are payable under the terms of a license agreement with Genentech Inc. ("Genentech"), which was the original developer of ACTIMMUNE and under the terms of its agreement with Connetics Corporation which was the predecessor parent company to InterMune Pharmaceuticals Inc. ("InterMune") and is now part of GlaxoSmithKline) ("Connetics"). See Note 14 for details of the percentages payable under both license agreements. The initial fair value of this liability of $33.6 million was determined using a discounted cash flow analysis incorporating the estimated future cash flows of royalty payments resulting from future sales. The discount rates used were the same as for the fair value of the intangible assets. The estimated liability for royalties will be increased over time to reflect the change in its present value and accretion expense will be recorded as part of cost of goods sold. The estimated liability will be periodically assessed based on events and circumstances and any change will be recorded in New Horizon's condensed consolidated statement of comprehensive income. During the second quarter of 2015, based on higher sales of ACTIMMUNE during the six months ended June 30, 2015 versus the Company's original expectations and the Company's adjusted expectations for future ACTIMMUNE sales, the Company recorded a charge of $5.4 million to cost of goods sold to increase the carrying value of the contingent royalties to reflect the updated estimates.

Deferred tax assets and liabilities arise from acquisition accounting 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 (United States or Bermuda). Customer relationships intangible assets are located in the United States where a U.S. tax rate of 39% is being utilized and a deferred tax liability is recorded. Developed technology and IPR&D assets are located in Bermuda which does not levy corporate income taxes; accordingly, no deferred tax liabilities were recorded related to these intangible assets.

The excess of the estimated fair values of net assets acquired over the acquisition consideration paid was recorded as a bargain purchase gain in the condensed consolidated statement of comprehensive income for the third quarter of 2014. As previously stated, the total consideration included a fixed number of New Horizon ordinary shares. The bargain purchase gain of $22.2 million was primarily the result of the decrease in the market value of our ordinary shares from the time that the Merger Agreement was signed to the Effective Time of the Vidara Merger.

Pro Forma Information

The following table represents the condensed consolidated financial information for the Company on a pro forma basis, assuming that the Vidara Merger and the Hyperion acquisition occurred as of January 1, 2014. For the nine months ended September 30, 2015, the Vidara Merger has already been reflected in the as reported figures as the Vidara Merger was completed in September 2014, and Hyperion results from May 7, 2015 to September 30, 2015 are also included in the 2015 as reported figures. The historical financial information has been adjusted to give effect to pro forma items that are directly attributable to the Vidara Merger and the Hyperion acquisition, 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. 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, except per share data):

	For the Nine Months Ended September 30,					
	2015			2014		
	As reported	Pro-forma adjustments (Unaudited)	Pro-forma (Unaudited)	As reported	Pro-forma adjustments (Unaudited)	Pro-forma (Unaudited)
Net sales	$512,506	$ 39,473	$ 551,979	$193,114	$ 133,343	$ 326,457
Net income (loss)	15,538	(25,703)	(10,165)	(231,956)	(10,998)	(242,954)
Basic net income (loss) per share	$0.11	$ (0.17)	$ (0.06)	$(3.17)	$ 0.78	$ (2.39)
Diluted net income (loss) per share	$0.10	$ (0.16)	$ (0.06)	$(3.17)	$ 0.78	$ (2.39)

Our condensed consolidated statements of comprehensive income for the three and nine months ended September 30, 2015 include RAVICTI and BUPHENYL net sales as a result of the acquisition of Hyperion in May 2015 of $37.4 million and $60.2 million, respectively. Our condensed consolidated statements of comprehensive income also include net sales of ACTIMMUNE of $28.7 million and $79.4 million for the three and nine months ended September 30, 2015, and net sales of $2.7 million for the three and nine months ended September 30, 2014 following the Vidara Merger on September 19, 2014. Hyperion and Vidara have been fully integrated into our business and as a result of these integration efforts, we cannot distinguish between these operations and those of our legacy business.

The 2014 pro forma information excludes the PENNSAID 2% acquisition as it was impracticable to include because it would require significant estimates of third-party sales amounts. In addition, prior to the Company's acquisition of PENNSAID 2%, PENNSAID 2% did not have a significant amount of sales in 2014.

NOTE 4 – INVENTORIES

Inventories are stated at the lower of cost or market value. Inventories consist of raw materials and work-in-process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture or 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, 2015 and December 31, 2014 consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Raw materials	$ 5,731	$ 1,184
Work-in-process	1,288	389
Finished goods	10,710	15,292
Inventories, net	$ 17,729	$ 16,865

Finished goods at December 31, 2014 included $3.2 million of stepped up ACTIMMUNE inventory which was fully amortized in January 2015.

Finished goods at September 30, 2015 included $1.2 million of stepped up RAVICTI and BUPHENYL inventory. In the second and third quarters 2015, the Company amortized $7.5 million of RAVICTI and BUPHENYL inventory step up.

NOTE 5 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets as of September 30, 2015 and December 31, 2014 consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Prepaid co-pay expenses	$ 1,824	$ 6,718
Product samples inventory	3,741	4,014
Prepaid software license fees	1,199	1,128
Other prepaid expenses	9,702	2,510
Prepaid expenses and other current assets	$ 16,466	$ 14,370

NOTE 6 – PROPERTY AND EQUIPMENT

Property and equipment as of September 30, 2015 and December 31, 2014 consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Machinery and equipment	$ 3,212	$ 3,288
Furniture and fixtures	704	576
Computer equipment	3,244	2,040
Software	2,452	1,481
Trade show equipment	228	392
Leasehold improvements	4,349	3,412
	14,189	11,189
Less-accumulated depreciation	(6,413)	(3,948)
Software implementation	2,604	—
Property and equipment, net	$ 10,380	$ 7,241

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 at September 30, 2015 is related to new enterprise resource planning software being implemented by the Company. The software is not yet in service and as such, depreciation has not yet begun.

Depreciation expense was $1.6 million and $0.4 million for the three months ended September 30, 2015 and 2014, respectively, and was $2.8 million and $1.2 million for the nine months ended September 30, 2015 and 2014,

respectively.

NOTE 7 – GOODWILL AND INTANGIBLE ASSETS

Goodwill

The gross carrying amount of goodwill as of September 30, 2015 was as follows (in thousands):

Balance at December 31, 2014	$—
Acquired during period	259,167
Balance at September 30, 2015	$259,167

In May 2015, the Company recognized goodwill with a preliminary value of $259.6 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 quarter ended September 30, 2015, the Company recorded measurement period adjustments that resulted in a net reduction in goodwill of $0.4 million, resulting in goodwill after the measurement period adjustments of $259.2 million (see Note 3 for details).

Intangible Assets

The Company’s intangible assets consist of developed technology related to the Company’s approved products, ACTIMMUNE, PENNSAID 2%, RAYOS, VIMOVO, RAVICTI and BUPHENYL in the United States and LODOTRA and AMMONAPS in Europe.

On September 19, 2014, in connection with the Vidara Merger, the Company capitalized $560.0 million of developed technology, $66.0 million of IPR&D and $8.1 million of customer relationships related to ACTIMMUNE.

On October 17, 2014, in connection with the Company's acquisition of the U.S. rights to PENNSAID 2%, the Company capitalized $45.0 million for the U.S. rights to developed technology of PENNSAID 2%.

On May 7, 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.

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, 2015 or December 31, 2014.

As of September 30, 2015 and December 31, 2014, amortizable intangible assets consisted of the following (in thousands):

	September 30, 2015				December 31, 2014			
	Cost Basis	Accumulated Amortization	Currency Translation	Net Book Value	Cost Basis	Accumulated Amortization	Currency Translation	Net Book Value
Developed technology	$1,792,495	$(141,942)	$—	$1,650,553	$757,484	$(51,331)	$(9,190)	$696,963
Customer relationships	8,100	(837)	—	7,263	8,100	(230)	—	7,870
Total amortizable intangible assets	$1,800,595	$(142,779)	$—	$1,657,816	$765,584	$(51,561)	$(9,190)	$704,833

Amortization expense for the three months ended September 30, 2015 and 2014 was $41.7 million and $6.4 million, respectively, and for the nine months ended September 30, 2015 and 2014 was $91.2 million and $16.5 million, respectively. IPR&D is not amortized until successful completion of the project. As of September 30, 2015, estimated future amortization expense was as follows (in thousands):

2015 (October to December)	$41,706
2016	166,826
2017	166,826
2018	166,826
2019	166,826
Thereafter	948,806
Total	$1,657,816

NOTE 8 - LONG-TERM INVESTMENTS

Long-term investments as of September 30, 2015 represented available-for-sale securities as follows (in thousands):

	September 30, 2015	December 31, 2014
Available-for-sale securities – non-current, at cost	$ 71,813	$ —
Unrealized losses	(29,400)	—
Total available-for-sale securities – non current	$ 42,413	$ —

From July 9, 2015 through August 24, 2015, the Company purchased 2,250,000 shares of Depomed common stock, representing 3.75% of Depomed's outstanding common stock. The shares were acquired at a cost of $71.8 million.

Unrealized losses of $29.4 million relate to the decrease in fair value of the investment. The Company believes this decrease in fair value is consistent with trends across the industry. The Company evaluated the near-term prospects of Depomed in relation to the severity and duration of the impairment. Based on that evaluation and the Company's ability and intent to hold these shares for a reasonable period of time sufficient for a forecasted recovery of fair value, the Company does not consider the decrease in fair value of the investment to be an "other than temporary" impairment as of September 30, 2015. Unrealized losses of $29.4 million have been recorded in comprehensive loss for the three and nine months ended September 30, 2015.

NOTE 9 – OTHER ASSETS

Other assets as of September 30, 2015 and December 31, 2014 consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Deferred financing costs	$ 8,737	$ 11,491
Other	777	73
Other assets	$ 9,514	$ 11,564

Costs incurred in connection with debt financings have been capitalized as deferred financing costs and are charged to interest expense using the effective interest method over the terms of the related debt agreements. These costs include document preparation costs, commissions, fees and expenses of investment bankers and underwriters, and accounting and legal fees.

NOTE 10 – ACCRUED TRADE DISCOUNTS AND REBATES

Accrued trade discounts and rebates as of September 30, 2015 and December 31, 2014 consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Accrued contractual allowances	$ 73,098	$ 55,678
Accrued government rebates and chargebacks	51,280	20,437
Accrued trade discounts and rebates	$ 124,378	$ 76,115
Invoiced contractual allowances and government rebates and chargebacks in accounts payable	42,753	5,221
Total customer-related accruals and allowances	$ 167,131	$ 81,336

Contractual allowances include co-pay assistance, product sales discounts and allowances, product launch discounts, customer rebates, distribution service fees, sales returns and prompt pay discounts.

The following table summarizes changes in the Company’s customer-related accruals and allowances from December 31, 2014 to September 30, 2015 (in thousands):

	Contractual	Government	Total

	Allowances	Rebates and Chargebacks	
Balance at December 31, 2014	$ 60,899	$ 20,437	$81,336
Current provisions relating to sales in the nine months ended September 30, 2015	719,217	113,034	832,251
Payments relating to sales in the nine months ended September 30, 2015	(620,381)	(59,906)	(680,287)
Payments relating to sales in prior years	(58,114)	(16,377)	(74,491)
Adjustments relating to prior year sales	(1,383)	(3,475)	(4,858)
Hyperion acquisition on May 7, 2015	244	12,936	13,180
Balance at September 30, 2015	$ 100,482	$ 66,649	$167,131

NOTE 11 – ACCRUED EXPENSES

Accrued expenses as of September 30, 2015 and December 31, 2014 consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Payroll-related expenses	$ 38,970	$ 20,933
Consulting services	12,241	4,421
Sales and marketing expenses	4,729	2,343
Deferred rent	1,252	1,026
Accrued interest	16,460	1,260
Accrued income taxes	1,864	1,400
Accrued other	8,848	3,999
Accrued excise tax	—	11,243
Accrued expenses	$ 84,364	$ 46,625

Accrued payroll-related expenses at September 30, 2015 include $11.4 million relating to severance and related employee costs as a result of the Hyperion acquisition.

NOTE 12 – ACCRUED ROYALTIES

Changes in the liability for royalties during the nine months ended September 30, 2015 consisted of the following (in thousands):

Balance as of December 31, 2014	$74,212
Assumed RAVICTI and BUPHENYL contingent royalty liabilities	86,800
Assumed RAVICTI and BUPHENYL accrued royalties	579
Remeasurement of royalty liabilities	14,277
Royalty payments	(18,756)
Accretion expense	13,571
Balance as of September 30, 2015	170,683
Less: Current portion	45,411
Accrued royalties, net of current	$125,272

During the second quarter of 2015, based on higher sales of ACTIMMUNE and VIMOVO during the six months ended June 30, 2015 versus the Company's original expectations and the Company's adjusted expectations for future ACTIMMUNE and VIMOVO sales, the Company recorded a total charge of $14.3 million to cost of goods sold ($8.9 million related to VIMOVO and $5.4 million related to ACTIMMUNE) to increase the carrying value of the contingent royalties to reflect the updated estimates. The Company did not record any remeasurements of the contingent royalties during the third quarter of 2015, as there were no triggering events during the period.

NOTE 13 – 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.

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, 2015, our cash and cash equivalents 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. There were no transfers between the different levels of the fair value hierarchy in 2015 or in 2014.

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, 2015 and December 31, 2014 (in thousands):

	September 30, 2015			
	Level 1	Level 2	Level 3	Total
Assets:				
Bank time deposits	$—	$50,000	$ —	$50,000
Money market funds	518,501	—	—	518,501
Long-term investments	42,413	—	—	42,413
Total assets at fair value	$560,914	$50,000	$ —	$610,914

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$111,581	$ —	$ —	$111,581
Total assets at fair value	$111,581	$ —	$ —	$111,581

In accordance with the pronouncement guidance in ASC Topic 815 “Derivatives and Hedging”, the conversion option included within the Convertible Senior Notes was deemed to include an embedded derivative, which required the Company to bifurcate and separately account for the embedded derivative as a separate liability on its condensed consolidated balance sheets. The estimated fair value was derived utilizing the binomial lattice approach for the valuation of convertible instruments. Assumptions used in the calculation included, among others, determining the appropriate credit spread using benchmarking analysis and solving for the implied credit spread, calculating the fair value of the stock component using a discounted risk free rate and borrowing cost and calculating the fair value of the note component using a discounted credit adjusted discount rate. Based on the assumptions used to determine the fair value of the derivative liability associated with the Convertible Senior Notes, the Company concluded that these inputs were Level 3 inputs.

The following table presents the assumptions used by the Company to determine the fair value of the conversion option embedded in the Convertible Senior Notes as of June 27, 2014, the date the HPI stockholders approved the issuance of in excess of 13,164,951 shares of HPI’s common stock upon conversion of the Convertible Senior Notes:

	June 27, 2014
Stock price	$15.96
Risk free rate	1.43 %
Borrowing cost	3.75 %
Weights	—
Credit spread (in basis points)	900
Volatility	40.00%
Initial conversion price	$5.36
Remaining time to maturity (in years)	4.4

On June 27, 2014, the Company conducted a fair value assessment to reflect the market value adjustments for the embedded derivative due to the increase in HPI’s common stock value and for changes in the fair value assumptions, and the Company recorded a $215.0 million loss in its results of operations for the three and six months ended June 30, 2014, respectively. The entire fair value of the derivative liability of $324.4 million was reclassified to additional paid-in capital on June 27, 2014.

NOTE 14 – COMMITMENTS AND CONTINGENCIES

Lease Obligations

As of September 30, 2015, the Company has the following lease agreements in place for real properties:

Location	Approximate Square Footage	Lease Expiry Date
Dublin, Ireland	10,300	November 4, 2029
Deerfield, Illinois	53,500	June 30, 2018
Chicago, Illinois	6,500	December 31, 2018
Mannheim, Germany	9,500	December 31, 2016
Reinach, Switzerland	3,500	May 31, 2020
Brisbane, California	20,100	November 30, 2019
Roswell, Georgia	6,200	October 31, 2018

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 five years from the date of first launch of RAYOS/LODOTRA in a major country, as defined in the agreement, which was during April 2009. Thereafter, the agreement automatically renews on a yearly basis until either party provides two years advance written notice of termination. In April 2015 the agreement automatically renewed, therefore the earliest the agreement can expire according to this advance notice procedure is April 15, 2018, and the minimum purchase commitment is in force until April 2018. At September 30, 2015, the minimum purchase commitment based on tablet pricing in effect under the agreement was $3.0 million through April 2018.

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 member states and Scandinavia. At September 30, 2015, the Company had a binding purchase commitment to sanofi-aventis U.S. for DUEXIS of $4.8 million, which is to be delivered through December 2015.

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. Under the agreement, Boehringer Ingelheim is required to manufacture and supply interferon gamma-1 b (ACTIMMUNE) to the Company. The Company is required to purchase minimum quantities of finished drug product per annum through July 2020. As of September 30, 2015, the minimum binding purchase commitment to Boehringer Ingelheim was $22.0 million (converted using a Dollar-to-Euro exchange rate of 1.1178).

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, 2015, the Company had a binding purchase commitment with Patheon for VIMOVO of $1.9 million.

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. Under the supply agreement, Nuvo is obligated to manufacture and supply PENNSAID 2% to the Company. The initial term of our supply agreement is through December 31, 2022, 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, 2015, the Company had a binding purchase commitment with Nuvo for PENNSAID 2% of $3.6 million.

Purchase orders relating to the manufacture of RAVICTI and BUPHENYL of $2.2 million were outstanding as at September 30, 2015.

Royalty Agreements

In connection with an August 2004 development and license agreement with SkyePharma AG ("SkyePharma") and Jagotec, a wholly-owned subsidiary of SkyePharma, regarding certain proprietary technology and know-how owned by SkyePharma, 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 sum and milestone payments.

Under a license agreement with Pozen Inc. (Pozen"), the Company is required to pay Pozen a flat 10% royalty on net sales of VIMOVO and other products 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 NSAIDs, subject to minimum annual royalty obligations of $7.5 million. These minimum royalty obligations will continue for each year during which one of Pozen's patents covers such products in the United States and there are no competing products 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 products. The Company's obligation to pay royalties to Pozen will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in the United States.

Under a license agreement with Genentech, which 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%-30% range for the first tier in net sales and in the 1%-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 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.

Under the terms of a collaboration agreement and asset purchase agreement with Ucyclyd, the Company is obligated to pay royalties to Ucyclyd on the Company's net sales as follows:

- Tiered mid to high single-digit royalties on global net sales of RAVICTI.
- Tiered mid to high single-digit royalties on net sales in the United States of BUPHENYL to urea cycle disorder patients outside of the FDA-approved labeled age range for RAVICTI.

The Company also licenses patented technology from Brusilow related to RAVICTI, and is obliged to pay royalties to Brusilow as follows:

- Low single-digit royalties on net sales of RAVICTI through 2025.

The royalty obligations for VIMOVO, ACTIMMUNE, RAVICTI and BUPHENYL are included in accrued royalties on the Company's condensed consolidated balance sheets.

Total royalty-related expense (including royalty accretion expense and royalty liability remeasurement expense) recognized in cost of goods sold for the three months ended September 30, 2015 and 2014 was $6.6 million and $2.7 million, respectively, and for the nine months ended September 30, 2015 and 2014 was $28.0 million and $18.7 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.

The Company previously entered into a rebate agreement with a PBM, pursuant to which the Company was required to pay certain rebates on certain of its products that were reimbursed by health plans contracting with the PBM with respect to their formularies. In 2014, the Company sent a notice alerting the PBM of certain material breaches by the PBM under the agreement and indicating that the agreement would automatically terminate if the material breaches were not cured within 30 days. Among other things, the breaches by the PBM involved repeated invoices that included claims for rebates which were not eligible for payment under the agreement. Following the 30-day period, during which the PBM did not take action to cure the breaches or formally respond to the notice, the Company sent another notice informing the PBM that the agreement was terminated as of the end of the 30-day period in accordance with its terms and the Company ceased paying further rebates under the agreement. On November 6, 2014 and March 9, 2015, the Company received letters from the PBM asserting that the breaches the Company alleged in its termination notice were not material breaches and therefore the agreement was not terminated and remains in effect. In addition, the PBM has claimed that the Company owes approximately $68.3 million in past price protection and utilization rebates related to VIMOVO and DUEXIS and further rebates on sales of VIMOVO and DUEXIS continuing after the date the Company believes the agreement was terminated. The substantial majority of these rebate claims relate to price protection rebates on VIMOVO which the Company believes are precluded under the agreement, particularly because VIMOVO was not covered under the agreement until after the Company had established an initial price for VIMOVO under a Horizon-owned National Drug Code. Based upon the terms of the agreement and the PBM's actions, the Company believes that the PBM's claims in its November 6, 2014 and March 9, 2015 letters are

without merit and the Company intends to vigorously defend against them. The Company currently estimates the range of potential disputes to be in the $0 to $4.7 million range and has not recorded a liability associated with any portion of the disputed amounts as the Company does not believe payment of any such amounts is probable at this time.

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. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, 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, 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. There have been no claims to date and the Company 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 have also entered into separate indemnification agreements with HPI prior to the Merger.

NOTE 15 – 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 affiliate 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 on-going patent infringement litigation. In accordance with legal requirements, the Company, Jagotec and Actavis FL have agreed to submit the Actavis Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The parties have agreed to file stipulations of dismissal with the court regarding the litigation. 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 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 in 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, they 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 November 13, 2014, the Company received a Paragraph IV Patent Certification from Actavis FL advising that Actavis FL had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Actavis FL has not advised the Company as to the timing or status of the FDA's review of its filing. On December 23, 2014, the Company filed suit in the United States District Court for the District of New Jersey against Actavis FL., Actavis, Inc., and Actavis plc (collectively "Actavis") seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges 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 generic versions of PENNSAID 2% prior to the expiration of the patents. The subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Actavis action.

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. And 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 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 the patents.

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 on-going patent infringement litigation. 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%.

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 in 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 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 the other parties.

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 before the expiration of 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 Limited and Lupin Pharmaceuticals Inc. (collectively, "Lupin"); (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, "Mylan"); and (iv) Watson Laboratories, Inc.—Florida, known as Actavis Laboratories FL, Inc. and Actavis Pharma, Inc. (collectively, "Actavis"). 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 Pozen 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 Pozen patents licensed to the Company under the amended and restated collaboration and license agreement for the United States with Pozen ("the Pozen license agreement").

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 and May 13, 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. On June 18, 2015, the Company amended the complaints to add a charge of infringement of U.S. Patent No. 8,865,190.

The cases asserting U.S. Patent Nos. 8,557,285 and 6,926,907 have been consolidated for discovery. The court has issued a claims construction order for these cases and has set a pretrial schedule, but has not yet set a trial date.

The cases asserting U.S. Patent Nos. 8,852,636, 8,858,996, and 8,865,190 have not been consolidated for discovery. The court has not issued a claims construction order or set a pretrial schedule.

The Company understands the cases arise from Paragraph IV 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 and February 9, 2015; the Actavis notice letters were dated March 29, 2013 November 5, 2013 and October 9, 2015; and the Anchen notice letter was dated September 16, 2011.

On February 24, 2015, Dr. Reddy's Laboratories, Inc. 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, Dr. Reddy's Laboratories, Inc.'s petition for inter partes review of U.S. Patent No. 8,557,285 was denied by the United States Patent and Trademark Office.

On May 21, 2015, the Coalition for Affordable Drugs VII LLC 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. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On June 5, 2015, the Coalition for Affordable Drugs VII LLC filed another Petition for IPR of U.S. Patent No. 8,858,996, one of the patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 7, 2015, the Coalition for Affordable Drugs VII LLC 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. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 12, 2015, the Coalition for Affordable Drugs VII LLC filed another Petition for IPR of U.S. Patent No. 8,945,621, one of the patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 19, 2015, Lupin filed Petitions for IPR of U.S. Patent Nos. 8,858,996, 8,852,636, and 8,865,190, all patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued decisions with regard to whether or not IPRs will be instituted.

On or about December 19, 2014, the Company filed a Notice of Opposition to a European patent, EP 2611457, to Roberto Testi, et al., covering compositions and methods for treating FA with interferon gamma, e.g., ACTIMMUNE. In the European Union, the grant of a patent may be opposed by one or more private 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 (the "Taro Settlement Agreement"), with Taro relating to our on-going patent infringement litigation. In accordance with legal requirements, the Horizon Subsidiaries and Taro have agreed to submit the Taro Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The Horizon Subsidiaries and Taro have also agreed to file stipulations of dismissal with the courts regarding the litigation. 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 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 in 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 Horizon'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 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%, they 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%. Lupin Limited has not advised the Company as to the timing or status of the FDA's review of its filing. On April 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Lupin, seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Lupin has infringed 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 the patents. The subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Lupin action.

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%.

The Company received from IGI Laboratories, Inc. ("IGI") 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 IGI had filed an ANDA with the FDA for a generic version of PENNSAID 2%. IGI has not advised the Company as to the timing or status of the FDA's review of its filing. On May 21, 2015, the Company filed suit in the United States District Court for the District of New Jersey against IGI seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that IGI 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 the patents. The subject patents are listed in the FDA's Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of IGI's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The court has not yet set a trial date for the IGI action.

On June 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against IGI 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 IGI 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 IGI 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%.

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%. Amneal has not advised the Company as to the timing or status of the FDA's review of its filing. 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 alleges 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 the patents. The subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Amneal action.

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 March 17, 2014, Hyperion received notice from Par Pharmaceutical, Inc. ("Par") that it had filed an ANDA with the FDA seeking approval for a generic version of the Company's product 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, and U.S. Patent No. 8,642,012, titled "Methods of treatment using ammonia scavenging drugs," which expires in September 2030, are invalid and/or will not be infringed by Par's manufacture, use or sale of the product for which the ANDA was submitted. Par 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 phenylalkenoic 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. Hyperion filed suit in the United States District Court for the Eastern District of Texas, Marshall Division, against Par on April 23, 2014 seeking an injunction to prevent the approval of Par's ANDA and/or to prevent Par 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 that it had filed a Paragraph IV Patent Certification alleging that U.S. Patent No. 9,095,559 is invalid and/or will not be infringed by Par's manufacture, use or sale of the product for which the ANDA was submitted.

On April 29, 2015, Par filed petitions for IPR of the '215 patent and the '012 patent. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not IPRs will be instituted.

The Company received from Lupin Limited a Paragraph IV Patent Certification dated September 4, 2015 against Orange Book listed U.S. Patent Nos. 8,404,215 and 8,642,012 advising that Lupin had filed an ANDA with the FDA for a generic version of RAVICTI. 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 U.S. Patent Nos. 8,404,215, 8,642,012, and 9,095,559 by filing an ANDA seeking approval from the FDA to market generic versions of RAVICTI prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. The 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. The court has not yet set a trial date for the Lupin action.

On August 3, 2015, HPI filed a lawsuit in the Superior Court of the State of California, County of Santa Clara, naming as defendants Depomed and the members of its board of directors (the "Depomed Board"), Vicente J. Anido, Jr., Karen

A. Dawes, Louis J. Lavigne, Jr., Samuel R. Saks, James A. Schoeneck, Peter D. Staple and David B. Zenoff. The lawsuit is captioned Horizon Pharma, Inc. v. Vicente J. Anido, Jr., et al., Case Number 1:15-cv-283835. The lawsuit alleges that the adoption by the Depomed Board of the Rights Agreement dated as of July 12, 2015 between Depomed and Continental Stock Transfer & Trust Company, as Rights Agent (the "Depomed Rights Agreement"), and Sections 2(b), 2(c), 2(d), and 5(d) of Depomed's Amended and Restated Bylaws, effective July 12, 2015 (the "Depomed Bylaws"), violates the General Corporation Law of the California Corporations Code, constitutes ultra vires acts and breaches the fiduciary duties of the members of the Depomed Board. The lawsuit seeks, among other things, an order (i) declaring that the Depomed Rights Agreement and Sections 2(b), 2(c), and 2(d) of the Depomed Bylaws are invalid under California law, (ii) declaring that the members of the Depomed Board breached their fiduciary duties by enacting the Depomed Rights Agreement and Sections 2(b), 2(c), 2(d), and 5(d) of the Depomed Bylaws, (iii) enjoining the members of the Depomed Board from relying on, implementing, applying or enforcing either the Depomed Rights Agreement or Sections 2(b), 2(c), 2(d), or 5(d) of the Depomed Bylaws, (iv) enjoining the members of the Depomed Board from taking any improper action designed to impede, or which has the effect of impeding, the proposed combination with Depomed or the Company's efforts to acquire control of Depomed and (v) compelling the members of the Depomed Board to redeem the Depomed Rights Agreement or to render it inapplicable to the Company. The Superior Court has calendared for November 5, 2015 a hearing on a preliminary injunction motion by HPI to enjoin enforcement of the Depomed Rights Agreement and Sections 2(b), 2(c) and 2(d) of the Depomed bylaws.

Also on August 3, 2015, Depomed filed a lawsuit in the Superior Court of the State of California, County of Santa Clara, against the Company. The lawsuit is captioned Depomed, Inc. v. Horizon Pharma plc, Case Number 1:15-cv-283834. The complaint asserts a claim for violation of the California Uniform Trade Secrets Act and breach of contract in connection with the Company's alleged use in pursuing the proposed combination with Depomed of information obtained pursuant to a confidentiality agreement entered into as part of the Company's consideration of a business arrangement with Janssen Pharmaceuticals Inc. relating to its U.S. rights to NUCYNTA®, which are now owned by Depomed. The complaint also alleges that the Company made fraudulent and materially misleading statements to Depomed's shareholders. The lawsuit seeks, among other relief, an injunction (i) to prevent the Company from continuing its allegedly improper and unlawful use of Depomed's confidential and trade secret data and (ii) to prevent the Company from continuing to make and failing to correct its allegedly false and misleading statements in connection with the proposed combination with Depomed. The Superior Court has calendared for November 5, 2015 a hearing on a preliminary injunction motion by Depomed.

NOTE 16 – DEBT AGREEMENTS

The Company's outstanding debt balances as of September 30, 2015 and December 31, 2014 consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
2023 Senior Notes	$475,000	$—
2015 Term Loan Facility due 2021	399,000	—
Exchangeable Senior Notes due 2022	400,000	—
2014 Term Loan Facility	—	300,000
Convertible Senior Notes	—	60,985
Debt discount	(132,989)	(15,482)
Total long-term debt	1,141,011	345,503
Less: current maturities	4,000	48,334
Long-term debt, net of current maturities	$1,137,011	$297,169

2023 Senior Notes

On April 29, 2015, Horizon Financing, a wholly-owned subsidiary of the Company, completed a private placement of $475.0 million aggregate principal amount of the Senior Notes (the "2023 Senior Notes"), to certain investment banks acting as initial purchasers who subsequently resold the 2023 Senior Notes to qualified institutional buyers as defined in Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"), and in offshore transactions to non-U.S. persons in reliance on Regulation S under the Securities Act.

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 (discussed 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 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.

As of September 30, 2015, the fair value of the 2023 Senior Notes was approximately $415.6 million, categorized as a Level 2 instrument, as defined in Note 13.

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 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 (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.

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, except that a 1% premium would apply to a repayment of the loans under the 2015 Term Loan Facility in connection with a repricing of, or any amendment to the 2015 Term Loan Facility in a repricing of, the loans under the 2015 Term Loan Facility effected on or prior to the date that is six months following May 7, 2015. 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 used the net proceeds from its April 2015 underwritten public offering of 17,652,500 of its ordinary shares at a price to the public of $28.25 per share (the “2015 Offering”), the offering of the 2023 Senior Notes, borrowings under the 2015 Term Loan Facility and existing cash to fund its acquisition of Hyperion, repay the outstanding amounts under the 2014 Term Loan Facility, and pay any prepayment premiums, fees and expenses in connection with the foregoing.

As of September 30, 2015, the fair value of the 2015 Term Loan Facility was approximately $389.0 million, categorized as a Level 2 instrument, as defined in Note 13.

Exchangeable Senior Notes

On March 13, 2015, Horizon Investment completed a private placement of $400.0 million aggregate principal amount of 2.50% Exchangeable Senior Notes due 2022 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.

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 ratably over the life of the Exchangeable Senior Notes.

As of September 30, 2015, the fair value of the Exchangeable Senior Notes was approximately $385.0 million, categorized as a Level 2 instrument, as defined in Note 13.

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”). The 2014 Senior Secured Credit Facility provided for (i) the committed five-year $300.0 million 2014 Term Loan Facility with a portion of the proceeds used to effect the Vidara Merger and to pay fees and expenses in connection therewith, and with the balance being used for general corporate purposes; (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. The initial borrower under the 2014 Term Loan Facility was U.S. HoldCo (renamed Horizon Pharma Holdings USA, Inc.). The credit agreement allowed for the Company and other subsidiaries of the Company to become borrowers under the accordion facility. Loans under the 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. The Company paid a ticking fee to the applicable lenders of $3.2 million covering the period beginning on the date that was 31 days following the effective date of the 2014 Senior Secured Credit Facility and continued through the closing of the Vidara Merger.

On May 7, 2015, the Company repaid the entire $300 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 Convertible Senior Notes and received net proceeds of $143.6 million, after deducting fees and expenses of $6.4 million.

Pursuant to a number of factors outlined in ASC Topic 815, Derivatives and Hedging, the conversion option in the Convertible Senior Notes was deemed to include an embedded derivative that required bifurcation and separate accounting. As such, the Company ascertained the value of the conversion option as if separate from the convertible issuance and appropriately recorded that value as a derivative liability. On November 22, 2013, a derivative liability and a corresponding debt discount in the amount of $40.1 million were recorded. The debt discount is being charged to interest expense ratably over the life of the convertible debt. The effective interest rate computed on the Convertible Senior Notes was 11.22%.

The derivative liability was subject to revaluation on a quarterly basis to reflect the market value change of the embedded conversion option. On June 27, 2014, HPI’s stockholders approved the issuance of shares of HPI’s common stock in excess of 13,164,951 shares upon conversion of the Convertible Senior Notes. As such, on the date of approval, the derivative liability was re-measured to a final fair value and the entire fair value of the derivative

liability of $324.4 million was reclassified to additional paid-in capital and the Company recorded a $215.0 million loss in its results of operations from remeasurement of the derivative liability.

In the fourth quarter of 2014, the Company entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes. Under the conversion agreements, the holders agreed to convert an aggregate principal amount of $89.0 million of Convertible Senior Notes held by them and the Company agreed to settle such conversions by issuing 16,594,793 ordinary shares. In addition, pursuant to the conversion agreements, the Company made an aggregate cash payment of $16.7 million to the holders for additional exchange consideration and $1.7 million of accrued and unpaid interest, and recognized a non-cash charge of $11.7 million related to the extinguishment of debt as a result of the note conversions.

In the first and second quarters of 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 17 – SHAREHOLDERS' EQUITY

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

During the nine months ended September 30, 2015, the Company issued an aggregate of 3,984,950 ordinary shares upon the cash exercise of warrants and the Company received proceeds of $18.1 million representing the aggregate exercise price for such warrants. In addition, warrants to purchase an aggregate of 1,090,952 ordinary shares of the Company were exercised in cashless exercises, resulting in the issuance of 887,559 ordinary shares. As of September 30, 2015, there were outstanding warrants to purchase 1,619,030 ordinary shares of the Company.

During the nine months ended September 30, 2015, the Company issued an aggregate of 711,546 ordinary shares in connection with the exercise of stock options and received $4.6 million in proceeds.

During the nine months ended September 30, 2015, in connection with the Convertible Senior Notes conversions, the Company issued an aggregate of 11,368,921 ordinary shares.

During the nine months ended September 30, 2015, the Company issued an aggregate of 376,083 ordinary shares pursuant to employee stock purchase plans and received $1.5 million in proceeds.

During the nine months ended September 30, 2015, the Company issued an aggregate of 255,162 ordinary shares in net settlement of vested restricted stock units.

NOTE 18 – SHARE-BASED INCENTIVE PLANS

Employee Stock Purchase Plans

2011 Employee Stock Purchase Plan. In July 2010, HPI's board of directors adopted the 2011 Employee Stock Purchase Plan (the "2011 ESPP"). In June 2011, HPI's stockholders approved the 2011 ESPP, and it became effective upon the signing of the underwriting agreement related to HPI's initial public offering in July 2011. Upon consummation of the Vidara Merger, the Company assumed the 2011 ESPP, and upon the effectiveness of the 2014

ESPP, no additional offerings were or will be commenced and no additional purchase rights were or will be granted under the 2011 ESPP, although all purchase rights outstanding under any offering that commenced under the 2011 ESPP prior to the Vidara Merger remain outstanding pursuant to their existing terms.

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, which serves as the successor to the 2011 ESPP.

As of September 30, 2015, an aggregate of 9,553,253 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 Incentive 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 14,000,000 shares. On May 6, 2015, 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 authorized for issuance under the 2014 Non-Employee Equity Plan is 2,500,000. 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, 2015, an aggregate of 1,838,748 and 2,277,007 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, 2015:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual	Aggregate Intrinsic Value

			Term	(in thousands)
Outstanding as of December 31, 2014	7,027,683	$ 8.95		
Granted	7,723,788	$ 24.10		
Exercised	(711,546)	$ 6.51		
Forfeited	(601,640)	$ 13.73		
Outstanding as of September 30, 2015	13,438,285	$ 17.58	8.59	$ 63,842
Exercisable as of September 30, 2015	3,338,592	$ 9.14	6.55	$ 36,570

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 stock 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, 2015 and 2014, and assumptions used to value stock options, are as follows:

	For the Nine Months Ended September 30,	
	2015	2014
Dividend yield	—	—
Risk-free interest rate	1.59 %	1.92 %
Weighted average volatility	77.1 %	83.06%
Expected life (in years)	6.04	6.02
Weighted average grant date fair value per share of options granted	$16.20	$8.77

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 (described in Note 16 above) contains 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 income (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, 2015:

	Number of Units	Weighted Average Grant-Date Fair Value Per Units
Outstanding as of December 31, 2014	1,593,502	$ 8.60
Granted	2,255,248	$ 23.55
Vested	(378,299)	$ 7.81
Forfeited	(77,400)	$ 15.10
Outstanding as of September 30, 2015	3,393,051	$ 18.48

Performance Stock Unit Awards

The following table summarizes performance stock unit awards ("PSUs") activity for the nine months ended September 30, 2015:

	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, 2014	25,000	$ 12.36	N/A	N/A
Granted	12,988,000	$ 15.07	14.5%	$ 12.89
Vested	—	N/A	N/A	N/A
Forfeited	(132,000)	$ 14.39	7.3%	$ 13.34
Outstanding as of September 30, 2015	12,881,000	$ 15.08	14.6%	$ 12.88

In March 2015, the compensation committee of the Company's board of directors (the "Committee") approved the grant of 10,604,000 PSUs to certain members of the Company's executive committee, senior leadership team and other key employees. 7,998,000 of these PSUs were granted subject to shareholder approval of certain amendments of the 2014 EIP, which occurred on May 6, 2015. In May 2015, the Committee granted 1,264,000 PSUs to new and promoted key employees. On August 5, 2015, the Committee granted 980,000 PSUs to a new member of the Company's Executive Committee and new key employees. On September 2, 2015, the Committee granted 140,000 PSUs to a promoted key employee.

The PSUs will 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

The PSUs will vest in amounts ranging from 25% to 100% based on the achievement of the following TSR over the three performance periods:

TSR	Vesting Amount

Achieved		
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. The 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 executive committee members and one year for 50% of the PSUs for non-executive committee members.

The Company accounts for the PSUs as equity-settled awards in accordance with ASC 718. Because the value of the PSUs 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. The average estimated fair value of each outstanding PSU granted under the 2014 EIP is as follows:

	Number of Units	Weighted Average Fair Value Per Unit	Average Illiquidity Discount		Recorded Weighted Average Fair Value Per Unit
Executive committee members	9,872,000	$ 15.12	17.1	%	$ 12.54
Non-executive committee members	2,984,000	$ 14.95	6.3	%	$ 14.00
	12,856,000	$ 15.08	14.6	%	$ 12.88

For the nine months ended September 30, 2015, the Company recorded $24.9 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 $16.5 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, 2015 and December 31, 2014, the estimated fair value was $5.4 million and $1.6 million, respectively. For the nine months ended September 30, 2015, the Company recorded $1.5 million of expense related to the Cash Bonus Program. The most significant valuation assumptions used as of September 30, 2015 include:

- Valuation Date Stock Price - $19.82.
- Expected Volatility - The expected volatility assumption of 71.69% is based on the Company's historical volatility over the 2.1 year period ending September 30, 2015, based upon daily stock price observations.
- Risk Free Rate - 0.67%, which is based upon the yield on U.S. Treasury Separate Trading of Registered Interest and Principal Securities with a remaining term of 2.1 years as of September 30, 2015.

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, 2015 and 2014 (in thousands):

	For the Nine Months Ended September 30,	
	2015	2014
Share-based compensation expense:		
Research and development	$4,712	$1,152
Sales and marketing	15,571	3,278
General and administrative	37,513	5,681
Total share-based compensation expense	$57,796	$10,111

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, 2015, the Company estimates that pre-tax unrecognized compensation expense of $322.6 million for all unvested share-based awards, including stock options, restricted stock units and PSUs, will be recognized through the third

quarter of 2019. 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 19 – 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 year that the change is enacted.

The following table presents the expense (benefit) for income taxes for the three and nine months ended September 30, 2015 and 2014 (in thousands):

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Profit (loss) before expense (benefit) for income taxes	$25,256	$(979)	$(121,250)	$(235,223)
Expense (benefit) for income taxes	21,979	(3,042)	(136,788)	(3,267)
Net income (loss)	$3,277	$2,063	$15,538	$(231,956)

During the nine months ended September 30, 2015, the Company recorded a benefit for income taxes of $136.8 million compared to an income tax benefit of $3.3 million during the nine months ended September 30, 2014. The increase in income tax benefit 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 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. 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 has been 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 740, 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 an existing U.S. federal and state valuation allowances. The deferred tax effect of unrealized losses recognized with respect to the decrease in fair value of the investment in Depomed common stock recorded in comprehensive loss during the three and nine months ended September 30, 2015 was fully offset by valuation allowances in the same periods.

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, 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 products, 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", "ma "plans", "projects", "will", "would" and similar expressions are intended to identify forward-looking 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.

MERGER WITH VIDARA

On September 19, 2014, the businesses of Horizon Pharma, Inc., or HPI, and Vidara Therapeutics International Public Limited Company, or Vidara, were combined in a merger transaction, or 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, or New Horizon. Upon the consummation of the Vidara Merger, the historical financial statements of HPI became our historical financial statements. Accordingly, the historical financial statements of HPI are included in the comparative prior periods.

Unless otherwise indicated or the context otherwise requires, references to the "Company", "New Horizon", "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 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 seven medicines through our orphan, primary care and specialty business units. Our U.S. marketed products are ACTIMMUNE® (interferon gamma-1b), BUPHENYL® (sodium phenylbutyrate) Tablets and Powder, DUEXIS® (ibuprofen/famotidine), PENNSAID® (diclofenac sodium topical solution) 2% w/w, RAVICTI® (glycerol phenylbutyrate) Oral liquid, RAYOS® (prednisone) Delayed-release tablets and VIMOVO® (naproxen/esomeprazole). We developed DUEXIS and RAYOS, known as LODOTRA® outside the United States, acquired the U.S. rights to VIMOVO from AstraZeneca AB, or AstraZeneca, in November 2013, acquired the U.S. rights to ACTIMMUNE as a result of the Vidara Merger, acquired the U.S. rights to PENNSAID 2% from Nuvo Research Inc., or Nuvo, in October 2014 and acquired RAVICTI and BUPHENYL, known as AMMONAPS® in Europe, as a result of the acquisition of Hyperion Therapeutics, Inc., or Hyperion, in May 2015. The CHMP of the EMA adopted a positive opinion at its plenary monthly meeting in September 2015 recommending a centralized marketing authorization for

RAVICTI for use as an adjunctive therapy for chronic management of adult and pediatric patients greater than two months of age with UCDs. The adopted positive opinion will be considered by the European Commission for a binding decision to be issued for the granting of a centralized marketing authorization, expected to be received within 60 to 90 days from the date of adoption of the opinion.

Our products are distributed by both retail and specialty pharmacies. A key part of our commercial strategy for our primary care and specialty business units is to offer physicians the opportunity to have their patients fill prescriptions through pharmacies who participate in the Prescriptions Made Easy, or PME, program. This program is not involved in the prescribing of medicines, and is solely to assist in ensuring that when a physician determines one of our medicines offers a potential clinical benefit to their patient and they prescribe one for an eligible patient, financial assistance may be available to reduce the patient's out-of-pocket costs. In the first nine months of 2015, this resulted in 96 percent of commercial patients having co-pay amounts of $10 or less when filling prescriptions for our products through PME. In addition, the aggregate commercial value of our patient support programs for the nine months ended September 30, 2015 was approximately $670 million. All pharmacies that fill prescriptions for our medicines are fully independent, including those that participate in the PME program, we do not own or possess any option to purchase an ownership stake in any pharmacy that distributes our products, and our relationship with each pharmacy is non-exclusive and arm's length. All of our sales are processed through pharmacies independent of the Company.

We have a compliance program in place to address adherence with various laws and regulations relating to our sales, marketing, and manufacturing of our products, 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 PME program, to confirm their activities, adjudication and practices are consistent with our compliance policies and guidance.

We market our products in the United States through our field sales force of approximately 402 representatives. Our strategy is to utilize the commercial strength and infrastructure we have established in creating a fully-integrated global biopharmaceutical company to continue the successful commercialization of our existing product portfolio while expanding and leveraging these capabilities further through the acquisition of biopharmaceutical products and companies.

RESULTS OF OPERATIONS

Comparison of Three Months Ended September 30, 2015 and 2014

The summary of selected financial data 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, 2015, compared to the three months ended September 30, 2014.

	For the Three Months Ended September 30,		
	2015	2014	Increase / (Decrease)
	(in thousands)		
Net sales	$226,544	$75,126	$151,418
Cost of goods sold	61,250	13,644	47,606
Gross profit	165,294	61,482	103,812
Operating expenses:			
Research and development	13,073	4,223	8,850
Sales and marketing	51,973	31,111	20,862
General and administrative	54,516	38,109	16,407
Total operating expenses	119,562	73,443	46,119
Operating income (loss)	45,732	(11,961)	57,693
Other (expense) income, net:			
Interest expense, net	(20,300)	(5,194)	(15,106)
Foreign exchange loss	(86)	(2,754)	2,668
Bargain purchase gain	—	22,171	(22,171)
Other expense, net	(90)	(3,241)	3,151
Total other (expense) income, net	(20,476)	10,982	(31,458)
Profit (loss) before expense (benefit) for income taxes	25,256	(979)	26,235
Income tax expense (benefit)	21,979	(3,042)	25,021
Net income	$3,277	$2,063	$1,214

Net sales. Net sales increased $151.4 million, or 202%, to $226.5 million during the three months ended September 30, 2015, from $75.1 million during the three months ended September 30, 2014.

Total net sales during the three months ending September 30, 2015 comprised $223.3 million related to net sales in the United States and $3.2 million related to net sales in the rest of the world, and total net sales during the three months ending September 30, 2014 comprised $74.3 million related to net sales in the United States and $0.8 million related to net sales in the rest of the world.

The following table reflects the components of net sales for the three months ended September 30, 2015 and 2014:

	Three Months Ended				
	September 30, 2015	2014	Change $	Change %	
	(in thousands)				
DUEXIS	$56,902	$22,753	$34,149	150	%
VIMOVO	46,855	43,206	3,649	8	%
PENNSAID 2%	43,892	—	43,892	*	
RAVICTI	33,427	—	33,427	*	
ACTIMMUNE	28,737	2,707	26,030	962	%
RAYOS	11,670	5,652	6,018	106	%
BUPHENYL	3,962	—	3,962	*	
LODOTRA	1,099	808	291	36	%
Total Net Sales	$226,544	$75,126	$151,418	202	%

*Percentage change is not meaningful.

The increase in net sales during the three months ended September 30, 2015 was primarily due to the recognition of PENNSAID 2% sales following our acquisition of the U.S. rights to PENNSAID 2% from Nuvo in October 2014, the recognition of RAVICTI and BUPHENYL sales following the acquisition of Hyperion in May 2015, the growth in net sales of DUEXIS, and full-period recognition of ACTIMMUNE sales during the three months ended September 30, 2015, compared with partial-period recognition during the three months ended September 30, 2014, following the Vidara Merger on September 19, 2014.

DUEXIS. Net sales increased $34.1 million, or 150%, to $56.9 million during the three months ended September 30, 2015, from $22.8 million during the three months ended September 30, 2014. DUEXIS net sales increased approximately $19.5 million due to higher net pricing resulting from wholesale acquisition cost, or WAC, price increases partially offset by additional patient co-pay reimbursements and increased approximately $14.6 million as the result of prescription volume growth driven by the expansion of our field sales force.

VIMOVO. Net sales increased $3.6 million to $46.9 million during the three months ended September 30, 2015, from $43.2 million during the three months ended September 30, 2014. VIMOVO net sales increased by approximately $6.5 million resulting from prescription volume growth, offset by approximately $2.9 million decrease due to lower net pricing. While we have increased the WAC price for VIMOVO over the past 12 months, the increases were offset by additional patient co-pay reimbursements.

PENNSAID 2%. Net sales were $43.9 million during the three months ended September 30, 2015. We began recognizing PENNSAID 2% sales in January 2015 following our acquisition of the U.S. rights to PENNSAID 2% from Nuvo in October 2014.

RAVICTI. Net sales were $33.4 million during the three months ended September 30, 2015. We began recognizing RAVICTI sales following the acquisition of Hyperion in May 2015.

ACTIMMUNE. Net sales increased $26.0 million to $28.7 million during the three months ended September 30, 2015, from $2.7 million during the three months ended September 30, 2014. We began recognizing ACTIMMUNE sales following the closing of the Vidara Merger on September 19, 2014, therefore only a partial period of

ACTIMMUNE sales were recognized during the three months ended September 30, 2014, compared with full-period recognition of sales during the three months ended September 30, 2015.

RAYOS. Net sales increased $6.0 million, or 106%, to $11.7 million during the three months ended September 30, 2015, from $5.7 million during the three months ended September 30, 2014. The increase was primarily due to prescription growth and net price increases resulting in higher net sales of approximately $5.1 million and $0.9 million, respectively.

BUPHENYL. Net sales were $4.0 million during the three months ended September 30, 2015. We began recognizing BUPHENYL sales following the acquisition of Hyperion in May 2015.

LODOTRA. Net sales increased $0.3 million, or 36%, to $1.1 million during the three months ended September 30, 2015, from $0.8 million during the three months ended September 30, 2014. The increase was primarily the result of higher product shipments to our European distribution partner, Mundipharma International Corporation Limited or Mundipharma. LODOTRA sales to Mundipharma occur at the time we ship product based on Mundipharma’s estimated requirement. Accordingly, LODOTRA sales are not linear or directly tied to Mundipharma’s in-market sales and can therefore fluctuate significantly from quarter to quarter.

Cost of Goods Sold. Cost of goods sold increased $47.7 million to $61.3 million during the three months ended September 30, 2015, from $13.6 million during the three months ended September 30, 2014. As a percentage of net sales, cost of goods sold was 27.0% during the three months ended September 30, 2015 compared to 18.2% during the three months ended September 30, 2014. The increase in cost of goods sold as a percentage of net sales was primarily attributable to an increase in intangible amortization expense of $35.1 million, a $6.1 million increase in product costs associated with higher sales, a $2.6 million increase in inventory step up amortization and higher royalty accretion expense of $3.9 million.

The increase in intangible amortization of $35.1 million during the three months ended September 30, 2015 compared to the prior year period was primarily due to intangible amortization expense of $24.0 million in relation to RAVICTI and BUPHENYL (acquired in May 2015), $9.3 million higher amortization expense relating to ACTIMMUNE developed technology (acquired on September 19, 2014) and $1.9 million relating to PENNSAID 2% (acquired in December 2014).

Research and Development Expenses. Research and development expenses increased $8.9 million to $13.1 million during the three months ended September 30, 2015, from $4.2 million during the three months ended September 30, 2014. The increase in research and development expenses during the three months ended September 30, 2015 was primarily associated with $7.4 million in research and development expenses for ACTIMMUNE, RAVICTI and BUPHENYL, which included $0.6 million of research and development in relation to the Phase 3 trial for Friedrich's ataxia, or FA.

Sales and Marketing Expenses. Sales and marketing expenses increased $20.9 million to $52.0 million during three months ended September 30, 2015, from $31.1 million during the three months ended September 30, 2014. The increase in sales and marketing expenses was in line with the significant growth in revenue and increase in the number of sales representatives over the same period and was primarily attributable to an increase of $11.6 million in employee costs, including $5.4 million related to share-based compensation resulting from increased staffing of our field sales force and expanding our PME program team, an increase of $3.6 million in product samples distributed and an increase of $3.2 million in marketing and commercialization expenses.

General and Administrative Expenses. General and administrative expenses increased $16.4 million to $54.5 million during the three months ended September 30, 2015, from $38.1 million during the three months ended September 30, 2014. The increase was attributable to $15.4 million of share-based compensation expense, $17.0 million related to our growth following the Hyperion acquisition and Vidara Merger, offset by $16.0 million of lower acquisition-related general and administrative expenses.

Interest Expense, Net. Interest expense, net, increased $15.1 million to $20.3 million during the three months ended September 30, 2015, from $5.2 million during the three months ended September 30, 2014. The increased interest expense, net, was primarily due to higher borrowings to fund the Vidara Merger in September 2014 and 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 the $400.0 million aggregate principal amount of 2.50% Exchangeable Senior Notes due 2022, or the Exchangeable Senior Notes, as compared to our prior year borrowings under our 5.00% Convertible Senior Notes due 2018, or Convertible Senior Notes, and the prior five-year $300.0 million term loan facility, or 2014 Term Loan Facility.

Foreign Exchange Loss. During the three months ended September 30, 2015, we reported a foreign exchange loss of $0.1 million.

Bargain Purchase Gain. During the three months ended September 30, 2014, we recorded a bargain purchase gain of $22.2 million in connection with the Vidara Merger, representing the excess of the estimated fair values of net assets acquired over the acquisition consideration paid.

Other Expense. Other expense during the three months ended September 30, 2015 decreased by $3.1 million to $0.1 million, from $3.2 million for the three months ended September 30, 2014. Other expense during the three months ended September 30, 2014 represented commitment fees incurred prior to the funding of the 2014 Term Loan Facility on September 19, 2014.

Income Tax Expense (Benefit). During the three months ended September 30, 2015, we recorded income tax expense of $22.0 million compared to income tax benefit of $3.0 million during the three months ended September 30, 2014. In the second quarter of 2015, we released valuation allowances on historical net operating losses and other deferred tax assets. As a result, future net operating losses and deferred tax assets in some tax jurisdictions will no longer have valuation allowances applied to them. In the third quarter, we had net operating income and recognized income tax expense of $22.0 million. The relatively high effective tax rate in the third quarter is primarily due to the timing and mix of operating income across different tax jurisdictions. For the full year, we continue to expect an overall tax benefit exclusive of the second quarter valuation allowance release.

Comparison of Nine Months Ended September 30, 2015 and 2014

The summary of selected financial data 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, 2015, compared to the nine months ended September 30, 2014.

	For the Nine Months Ended		
	September 30,		Increase / (Decrease)
	2015	2014	
	(in thousands)		
Net sales	$512,506	$193,114	$319,392
Cost of goods sold	151,929	46,073	105,856
Gross profit	360,577	147,041	213,536
Operating expenses:			
Research and development	28,176	10,601	17,575
Sales and marketing	157,092	86,932	70,160
General and administrative	157,986	66,982	91,004
Total operating expenses	343,254	164,515	178,739
Operating income (loss)	17,323	(17,474)	34,797
Other (expense) income, net:			
Interest expense, net	(49,780)	(13,608)	(36,172)
Foreign exchange loss	(1,010)	(3,076)	2,066
Loss on derivative fair value	—	(214,995)	214,995
Bargain purchase gain	—	22,171	(22,171)
Loss on induced conversion of debt and debt extinguishment	(77,624)	—	(77,624)
Other expense	(10,159)	(8,241)	(1,918)
Total other expense, net	(138,573)	(217,749)	79,176
Loss before benefit for income taxes	(121,250)	(235,223)	113,973
Income tax benefit	(136,788)	(3,267)	(133,521)
Net income (loss)	$15,538	$(231,956)	$247,494

Net sales. Net sales increased $319.4 million, or 165%, to $512.5 million during the nine months ended September 30, 2015, from $193.1 million during the nine months ended September 30, 2014.

Total net sales during the nine months ending September 30, 2015 comprised $505.2 million related to net sales in the United States and $7.3 million related to net sales in the rest of the world, and total net sales during the nine months ending September 30, 2014 comprised $189.7 million related to net sales in the United States and $3.4 million related to net sales in the rest of the world.

The following table reflects the components of net sales for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended		
	September 30,	Change	Change

	2015	2014	$	%
		(in thousands)		
DUEXIS	$129,981	$54,465	$75,516	139 %
VIMOVO	119,628	119,622	6	0 %
PENNSAID 2%	91,583	—	91,583	*
ACTIMMUNE	79,369	2,707	76,662	2,832 %
RAVICTI	52,420	—	52,420	*
RAYOS	29,191	12,898	16,293	126 %
BUPHENYL	7,822	—	7,822	*
LODOTRA	2,512	3,422	(910)	(27 %)
Total Net Sales	$512,506	$193,114	$319,392	165 %

*Percentage change is not meaningful.

The increase in net sales during the nine months ended September 30, 2015 was primarily due the recognition of PENNSAID 2% sales following our acquisition of the U.S. rights to PENNSAID 2% from Nuvo in October 2014, the recognition of RAVICTI and BUPHENYL sales following the acquisition of Hyperion in May 2015, the growth in sales of DUEXIS and RAYOS/LODOTRA and full-period recognition of ACTIMMUNE sales during the nine months ended September 30, 2015, compared with partial-period recognition during the nine months ended September 30, 2014, following the Vidara Merger on September 19, 2014.

DUEXIS. Net sales increased $75.5 million, or 139%, to $130.0 million during the nine months ended September 30, 2015, from $54.5 million during the nine months ended September 30, 2014. DUEXIS net sales increased $37.8 million as the result of prescription volume growth driven by the expansion of our field sales force and increased $37.7 million due to higher net pricing resulting from WAC price increases partially offset by additional patient co-pay reimbursements.

VIMOVO. Net sales were $119.6 million during both the nine months ended September 30, 2015 and the nine months ended September 30, 2014. VIMOVO net sales decreased approximately $13.3 million due to lower net pricing, offset by $13.3 million resulting from prescription volume growth. While we have increased the WAC price for VIMOVO over the last 12 months, the increases were offset in part by additional patient co-pay reimbursements.

PENNSAID 2%. Net sales were $91.6 million during the nine months ended September 30, 2015. We began recognizing PENNSAID 2% sales in January 2015 following our acquisition of the U.S. rights to PENNSAID 2% from Nuvo in October 2014.

ACTIMMUNE. Net sales increased $76.7 million to $79.4 million during the nine months ended September 30, 2015, from $2.7 million during the nine months ended September 30, 2014. We began recognizing ACTIMMUNE sales following the closing of the Vidara Merger on September 19, 2014, therefore only a partial period of ACTIMMUNE sales were recognized during the nine months ended September 30, 2014, compared with full-period recognition of sales during the nine months ended September 30, 2015.

RAVICTI. Net sales were $52.4 million during the nine months ended September 30, 2015. We began recognizing RAVICTI sales following the acquisition of Hyperion in May 2015.

RAYOS. Net sales increased $16.3 million, or 126%, to $29.2 million during the nine months ended September 30, 2015, from $12.9 million during the nine months ended September 30, 2014. The increase was primarily due to prescription growth and net price increases resulting in higher net sales of approximately $12.2 million and $4.1 million, respectively.

BUPHENYL. Net sales were $7.8 million during the nine months ended September 30, 2015. We began recognizing BUPHENYL sales following the acquisition of Hyperion in May 2015.

LODOTRA. Net sales decreased $0.9 million, or 27%, to $2.5 million during the nine months ended September 30, 2015, from $3.4 million during the nine months ended September 30, 2014. The decrease was primarily the result of fewer product shipments to our European distribution partner, Mundipharma International Corporation Limited or Mundipharma. LODOTRA sales to Mundipharma occur at the time we ship product based on Mundipharma’s estimated requirement. Accordingly, LODOTRA sales are not linear or directly tied to Mundipharma’s in-market sales and can therefore fluctuate significantly.

We currently expect our net sales to continue to increase in 2015 and future periods compared to 2014 as a result of volume growth as well as net price increases. While we believe WAC price increases enacted in the last twelve months should continue to favorably impact net sales during 2015, they will be offset in part by additional patient co-pay reimbursements, rebates, fees and other costs included within net sales.

Effective January 1, 2015, two significant PBMs placed DUEXIS and VIMOVO on their exclusion lists, which resulted in a loss of reimbursement for patients whose healthcare plans have adopted these PBM exclusion lists. However, this action did not negatively impact sales volume for either product. In fact, with successful adoption of our PME program by physicians, we are seeing increases in sales volume for both products. During the nine months ended September 30, 2015, DUEXIS volumes have increased by 69% and VIMOVO volumes have increased by 11%, when compared to the nine months ended September 30, 2014.

We have expanded and plan to continue expanding our sales force to support existing and newly acquired products such as PENNSAID 2% which we acquired in October 2014 and began marketing in January 2015. As result of the Hyperion acquisition, Vidara Merger and our acquisition of PENNSAID 2%, we expanded our sales force to approximately 402 sales representatives, consisting of 349 primary care sales representatives, 44 specialty sales representatives and 9 orphan disease sales representatives, from 310 sales representatives on June 30, 2014.

Cost of Goods Sold. Cost of goods sold increased $105.8 million to $151.9 million during the nine months ended September 30, 2015, from $46.1 million during the nine months ended September 30, 2014. As a percentage of net sales, cost of goods sold was 29.6% during the nine months ended September 30, 2015 compared to 23.9% during the nine months ended September 30, 2014. The increase in cost of goods sold was primarily attributable to an increase in intangible amortization expense of $74.2 million, a $13.6 million increase in product costs associated with higher sales, $9.1 million increase in inventory step up amortization relating to ACTIMMUNE, RAVICTI and BUPHENYL, higher royalty accretion expense of $8.0 million and a $1.2 million increase in charges relating to the remeasurement of contingent royalty liabilities.

The increase in intangible amortization of $74.2 million during the nine months ended September 30, 2015 compared to the prior year period was primarily due to intangible amortization expense of $38.2 million in relation to RAVICTI and BUPHENYL (acquired in May 2015), $30.9 million relating to ACTIMMUNE developed technology (acquired on September 19, 2014) and $5.6 million relating to PENNSAID 2% (acquired in December 2014).

Research and Development Expenses. Research and development expenses increased $17.6 million to $28.2 million during the nine months ended September 30, 2015, from $10.6 million during the nine months ended September 30, 2014. The increase in research and development expenses during the nine months ended September 30, 2015 was primarily associated with $13.2 million in research and development expenses for ACTIMMUNE, RAVICTI and BUPHENYL. This included $2.1 million of research and development in relation to the Phase 3 trial for FA. We have also recorded an increase in acquisition-related research and development expenses during the nine months ended September 30, 2015 of $2.3 million compared with the nine months ended September 30, 2014.

Sales and Marketing Expenses. Sales and marketing expenses increased $70.2 million to $157.1 million during the nine months ended September 30, 2015, from $86.9 million during the nine months ended September 30, 2014. The increase in sales and marketing expenses is in line with the growth in revenue and increase in the number of sales representatives over the same period, and was primarily attributable to an increase of $43.7 million in employee costs, including $12.3 million related to share-based compensation resulting from increased staffing of our field sales force and expanding our PME program team, an increase of $14.4 million in marketing and commercialization expenses and an increase of $5.6 million in product samples distributed.

General and Administrative Expenses. General and administrative expenses increased $91.0 million to $158.0 million during the nine months ended September 30, 2015, from $67.0 million during the nine months ended September 30, 2014. The increase in general and administrative expenses was primarily attributable to $31.8 million in share-based compensation expense, $15.1 million in acquisition-related general and administrative expenses and $44.1 million related to our growth following the Hyperion acquisition and Vidara Merger.

Interest Expense, Net. Interest expense, net increased $36.2 million to $49.8 million during the nine months ended September 30, 2015, from $13.6 million during the nine months ended September 30, 2014. The increased interest expense, net was primarily due to higher borrowings to fund the Vidara Merger in September 2014 and the acquisition of Hyperion in May 2015, including our 2023 Senior Notes, the 2015 Term Loan Facility and the Exchangeable Senior Notes, as compared to our prior year borrowings under our Convertible Senior Notes, and the 2014 Term Loan Facility.

Foreign Exchange Loss. During the nine months ended September 30, 2015, we reported a foreign exchange loss of $1.0 million.

Bargain Purchase Gain. During the nine months ended September 30, 2014, we recorded a bargain purchase gain of $22.2 million in connection with the Vidara Merger, representing the excess of the estimated fair values of net assets acquired over the acquisition consideration paid.

Loss on Derivative Revaluation. During the nine months ended September 30, 2014, we recorded a $215.0 million non-cash charge related to the increase in the fair value of the embedded derivative associated with our Convertible Senior Notes. The loss on the derivative revaluation was primarily due to an increase in the market value of HPI's common stock during the period from January 1, 2014 until June 27, 2014, the date HPI's stockholders approved the issuance of in excess of 13,164,951 shares of HPI's common stock upon conversion of the Convertible Senior Notes. The derivative liability was re-measured to a final fair value and the entire fair value of the derivative liability of $324.4 million was reclassified to additional paid-in capital. As such, there was no derivative revaluation subsequent to June 2014.

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 comprised of $20.7 million related to the induced conversions of 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 a $11.5 million charge for the extinguishment of debt.

Other Expense. Other expense during the nine months ended September 30, 2015 totaled $10.2 million, which primarily included the fees related to the Hyperion acquisition financing commitment. Other expense during the nine months ended September 30, 2014 totaled $8.2 million representing commitment fees incurred on the bridge financing in place prior to executing the 2014 Term Loan Facility in June 2014, along with commitment fees incurred on the 2014 Term Loan Facility prior to its funding on September 19, 2014.

Income Tax Expense (Benefit). During the nine months ended September 30, 2015, we recorded income tax benefit of $136.8 million compared to income tax benefit of $3.3 million during the nine months ended September 30, 2014. The recognition of income tax benefit during the nine months ended September 30, 2015 was primarily attributable to the release of $105.0 million in valuation allowances in the U.S. tax consolidation group due to the recognition of significant deferred tax liabilities as a result of the Hyperion acquisition, as well as the ability to recognize tax benefit for our U.S. tax consolidation group losses projected to be incurred for the full year.

NON-GAAP FINANCIAL MEASURES

To supplement our financial results presented under U.S. generally accepted accounting principles, or GAAP, we have included information about non-GAAP financial measures used by us which may be calculated differently from, and therefore may not be comparable to, non-GAAP measures used by other companies. We include information about adjusted non-GAAP net income, adjusted non-GAAP net income per share, EBITDA, or earnings before interest, tax, depreciation and amortization, and adjusted EBITDA as useful operating metrics for the three and nine month periods ended September 30, 2015 and 2014. We believe that the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliations, provides supplementary information to investors and can enhance an overall understanding of Horizon’s financial performance. Due to the expanding nature of our business, we use these non-GAAP financial measures in connection with our own planning and forecasting purposes and for measuring our performance. These non-GAAP financial measures should be considered in addition to, and not a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP. Non-GAAP adjusted net income and non-GAAP adjusted net income per share are not based on any standardized methodology prescribed by GAAP and represent GAAP net income (loss) and GAAP net income (loss) per share adjusted to exclude, as applicable, remeasurement of royalties for products acquired through business combinations, transaction and integration costs, royalty accretion expense, intangible asset amortization, share-based compensation expense, depreciation expense, acquisition accounting inventory fair value step up adjustments, loss on derivative revaluation, loss on induced conversion and extinguishment of debt, amortization of debt discount and deferred financing costs, bargain purchase gain, and adjusts the income tax provision to the estimated amount of taxes payable in cash. In addition, we include in non-GAAP adjusted net income royalties for products acquired through business combinations (and the related per share measures).

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
GAAP net income (loss)	$3,277	$2,063	$15,538	$(231,956)
Non-GAAP Adjustments:				
Remeasurement of royalties for products acquired through business combinations (1)	—	—	14,277	13,033
Acquisition-related costs	14,498	31,477	64,841	45,651
Loss on derivative revaluation	—	—	—	214,995
Loss on induced conversion of debt and debt extinguishment	—	—	77,624	—
Bargain purchase gain	—	(22,171)	—	(22,171)
Amortization and accretion:				
Intangible amortization expense	41,707	6,413	91,217	16,469
Amortization of debt discount and deferred financing costs	5,480	2,421	13,328	7,087
Accretion of royalty liabilities	6,551	2,664	13,571	5,617
Amortization of inventory step up adjustment	4,140	1,540	10,635	1,540
Share-based compensation	26,457	4,024	57,796	10,111
Depreciation expense	1,578	413	2,808	1,193
Royalties for products acquired through business combinations (1)	(8,854)	(6,366)	(20,890)	(12,062)
Income tax adjustments (2)	22,178	(3,042)	(137,328)	(3,267)
Adjusted non-GAAP net income	117,012	19,436	203,417	46,240
Adjusted non-GAAP earnings per share:				
Weighted average shares – Basic	159,035,580	78,392,971	145,208,252	73,109,603
Adjusted non-GAAP earnings per share – Basic				
GAAP earnings (loss) per share basic	$0.02	$0.03	$0.11	$(3.17)
Non-GAAP adjustments	0.72	0.22	1.29	3.80
Adjusted non-GAAP earnings per share – Basic	$0.74	$0.25	$1.40	$0.63
Weighted average shares – Diluted				
Weighted average shares – Basic	159,035,580	78,392,971	145,208,252	73,109,603
Ordinary share equivalents	7,795,220	35,258,496	8,797,419	35,577,854
Weighted average shares – Diluted	166,830,800	113,651,467	154,005,671	108,687,457
Adjusted non-GAAP net income – Diluted				
Adjusted non-GAAP net income	$117,012	$19,436	$203,417	$46,240
Add: Convertible debt interest expense, net of taxes	—	1,875	—	5,625
Adjusted non-GAAP net income – Diluted	$117,012	$21,311	$203,417	$51,865
GAAP earnings (loss) per share – Diluted	$0.02	$0.02	$0.10	$(3.17)
Non-GAAP adjustments	0.68	0.20	1.22	3.81

Diluted earnings per share effect of ordinary share equivalents	—	(0.03)	—	(0.16)
Adjusted non-GAAP earnings per share – Diluted	$0.70	$0.19	$1.32	$0.48

(1) Royalties for products acquired through business combinations relate to VIMOVO, ACTIMMUNE, RAVICTI and BUPHENYL.
(2) Adjustments to convert the income tax benefit/expense to the estimated amount of taxes that are payable in cash.

The following table reconciles the Company's reported GAAP net income (loss) to adjusted EBITDA for the three and nine months ended September 30, 2015 and 2014 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
GAAP net income (loss)	$3,277	$2,063	$15,538	$(231,956)
Depreciation	1,578	413	2,808	1,193
Amortization and accretion:				
Intangible amortization expense	41,707	6,413	91,217	16,469
Amortization of deferred revenue	(490)	(156)	(753)	(478)
Accretion of royalty liabilities	6,551	2,664	13,571	5,617
Amortization of inventory step up adjustment	4,140	1,540	10,635	1,540
Interest expense, net (including amortization of debt discount and deferred financing costs)	20,300	5,194	49,780	13,608
Expense (benefit) for income taxes	21,979	(3,042)	(136,788)	(3,267)
EBITDA	99,042	15,089	46,008	(197,274)
Non-GAAP adjustments:				
Remeasurement of royalties for products acquired through business combinations (1)	—	—	14,277	13,033
Acquisition-related costs	14,498	31,477	64,841	45,651
Loss on derivative revaluation	—	—	—	214,995
Loss on induced conversion and debt extinguishment	—	—	77,624	—
Bargain purchase gain	—	(22,171)	—	(22,171)
Share-based compensation	26,457	4,024	57,796	10,111
Royalties for products acquired through business combinations (1)	(8,854)	(6,366)	(20,890)	(12,062)
Total of non-GAAP adjustments	32,101	6,964	193,648	249,557
Adjusted EBITDA	$131,143	$22,053	$239,656	$52,283

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

LIQUIDITY, FINANCIAL POSITION AND CAPITAL RESOURCES

We have incurred losses since our inception in June 2005 and, as of September 30, 2015, we had an accumulated deficit of $705.2 million. We expect that our sales and marketing expenses will continue to increase as a result of our commercialization of our products, but we believe these cost increases will be more than offset by higher net sales and gross profits and we expect our current operations to achieve profitability in 2015, absent unusual or non-recurring items.

We have financed our operations to date through equity financings, debt financings and the issuance of convertible notes. As of September 30, 2015, we had $684.3 million in cash and cash equivalents and total debt with a book value

of $1,141.0 million and face value of $1,274.0 million. We believe we will generate sufficient cash flows from our operations 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 or in-licensing and commercializing additional differentiated products that address unmet medical needs. To the extent we enter into transactions to acquire products 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 the fourth quarter of 2014, we entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes. Under the conversion agreements, the holders agreed to convert an aggregate principal amount of $89.0 million of Convertible Senior Notes held by them and we agreed to settle such conversions by issuing 16,594,793 ordinary shares. In addition, pursuant to the conversion agreements, we made an aggregate cash payment of $16.7 million to the holders for additional exchange consideration and $1.7 million of accrued and unpaid interest.

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 of 1933, as amended, or 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 us, 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 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.

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 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. 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, or 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%. We borrowed the full $400.0 million available under the 2015 Term Loan Facility on May 7, 2015 as a LIBOR-based borrowing.

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, except that a 1% premium would apply to a repayment of the loans under the 2015 Term Loan Facility in connection with a repricing of, or any amendment to the 2015 Term Loan Facility in a repricing of, the loans under the 2015 Term Loan Facility effected on or prior to the date that is six months following May 7, 2015. 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 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.

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 indenture governing the 2023 Senior Notes and the credit agreement related to the 2015 Senior Secured Credit 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, 2015, we received proceeds of $18.1 million in connection with our issuance of an aggregate of 4,872,509 of our ordinary shares upon the exercise of warrants. Additionally, we issued an aggregate of 711,546 ordinary shares in connection with the exercise of stock options and received $4.6 million in proceeds.

We are required to maintain compliance with applicable Swiss laws with respect to our Swiss subsidiary, Horizon Pharma Switzerland GmbH, including laws requiring maintenance of equity in the subsidiary to avoid over-indebtedness, which requires Horizon Pharma Switzerland GmbH to maintain assets in excess of its liabilities. We review on a regular basis whether Horizon Pharma Switzerland GmbH is over-indebted. As of September 30, 2015, Horizon Pharma Switzerland GmbH was not over-indebted. However, Horizon Pharma Switzerland GmbH has previously been over-indebted. We will continue to monitor and review Horizon Pharma Switzerland GmbH's financial position and, as necessary, will address any over-indebtedness until such time as Horizon Pharma Switzerland GmbH generates positive income at a statutory level, which could require us to have cash at Horizon Pharma Switzerland GmbH in excess of its near-term operating needs and could affect our ability to have sufficient cash to meet the near-term operating needs of our other operating subsidiaries. As of September 30, 2015 and December 31, 2014, Horizon Pharma Switzerland GmbH had cash and cash equivalents of $1.0 million and $3.0 million, respectively. Based upon the cash and cash equivalents held by Horizon Pharma Switzerland GmbH as of September 30, 2015 and December 31, 2014, we do not expect that our financial position or results of operations will be materially affected by any need to address over-indebtedness at Horizon Pharma Switzerland GmbH. To date, the over-indebtedness of Horizon Pharma Switzerland GmbH has not resulted in the need to divert material cash resources from our other operating subsidiaries.

Sources and Uses of Cash

The following table provides a summary of our cash position and cash flows for the nine months ended September 30, 2015 and 2014 (in thousands):

	Nine Months Ended September 30,	
	2015	2014
Cash and cash equivalents	$684,286	$248,781
Cash provided by (used in):		
Operating activities	59,228	17,470
Investing activities	(1,034,187)	(181,057)
Financing activities	1,440,587	331,966

Operating Cash Flows

During the nine months ended September 30, 2015, net cash provided by operating activities was $59.2 million compared to $17.5 million during the nine months ended September 30, 2014. 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 product sales, partially offset by higher cash outlays for contractual allowances and government rebates and chargebacks. Cash provided by operating activities was negatively impacted during the nine months ended September 30, 2015 due to cash payments of $32.9 million of costs related to the Hyperion acquisition, the payment in April 2015 of approximately $11.2 million of employee and director-related excise taxes due to the Vidara Merger, the payment of a $45.4 million early redemption premium related to 2014 Term Loan Facility, $21.4 million of interest payments made on our 2014 Term Loan Facility, 2015 Term Loan Facility and Exchangeable Senior Notes, and $10.5 million of cash payments related to induced debt conversions.

Investing Cash Flows

During the nine months ended September 30, 2015 and 2014, net cash used in investing activities was $1,034.2 million and $181.1 million, respectively. The increase in net cash used in investing activities during the nine months ended September 30, 2015 was primarily associated with $1,022.4 million of payments for the acquisition of Hyperion, net of cash acquired, and payments of $71.8 million were also made in relation to the purchase of 2,250,000 shares of Depomed common stock. This was offset by proceeds of $64.6 million from the liquidation of available-for-sale investments.

Financing Cash Flows

During the nine months ended September 30, 2015, net cash provided by financing activities was $1,440.6 million compared to $332.0 million during the nine months ended September 30, 2014. The increase in net cash provided by financing activities during the nine months ended September 30, 2015 was primarily attributable to $387.2 million of net proceeds received from borrowings under the Exchangeable Senior Notes, $391.5 million net proceeds from the 2015 Term Loan Facility, $462.3 million net proceeds from the 2023 Senior Notes and $475.6 million of net proceeds from the issuance of 17,652,500 ordinary shares in the 2015 Offering, partially offset by the repayment of the 2014 Term Loan Facility and a partial repayment of the 2015 Term Loan Facility, which resulted in a financing outflow of $298.0 million.

Contractual Obligations

During the nine months ended September 30, 2015, 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, 2014, except for the changes described below.

On March 13, 2015, Horizon Investment completed a private placement of $400 million aggregate principal amount of the 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.

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 April 29, 2015, we completed a private placement of $475 million aggregate principal amount of 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.

On May 7, 2015, we entered into the 2015 Senior Secured Credit Facility and HPI borrowed the entire $400.0 million available under the 2015 Term Loan Facility. 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 3.5% per annum (subject to a 1.00% 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 initial borrowing on May 7, 2015 was made as a LIBOR-based borrowing.

In September 2014, Hyperion acquired Andromeda Biotech Ltd., or Andromeda, an Israeli company developing DiaPep277® for the treatment of recent onset Type 1 diabetes, from Clal Biotechnologies Industries Ltd., or CBI. In February 2015, Hyperion entered into a Completion of Phase 3 Clinical Trial, Option and Mutual Release Agreement, or the CBI/Yeda Agreement, with CBI and Yeda Research and Development Company Ltd, or Yeda, the company from which Andromeda licenses the underlying DiaPep277 technology. Under the CBI/Yeda Agreement, Hyperion committed to complete the on-going Phase 3 clinical trial of DiaPep277, without exceeding the original budget of $10.5 million. Total clinical trial cost incurred through September 30, 2015 was $6.8 million. The estimated costs of the clinical trial from May 7, 2015, the Hyperion acquisition date, until the completion of the clinical trial, which is scheduled to be completed prior to January 2016, are expected to be approximately $3.0 million. As a result, we have established a reserve in the Hyperion opening balance sheet in purchase accounting for the $3.0 million in costs to complete the Phase 3 clinical trial.

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, 2014. There have been no significant changes in our application of our critical accounting policies during the nine months ended September 30, 2015, except as noted below.

Goodwill

Goodwill represents the excess of the purchase price of acquired businesses over the estimated fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment at least annually at the reporting unit level or more frequently if events or changes in circumstances indicate that the asset might be impaired. Impairment loss, if any, is recognized based on a comparison of the fair value of the asset to its carrying value, without consideration of any recoverability. We expect to test goodwill for impairment annually during the fourth quarter.

In May 2015, we recognized goodwill with a preliminary value of $259.6 million in connection with the Hyperion acquisition, which goodwill represented the excess of the purchase price over the fair value of the net assets acquired. During the quarter ended September 30, 2015, we recorded measurement period adjustments which resulted in goodwill after the measurement period adjustments of $259.2 million.

Available-For-Sale Securities

The Company's long-term investments are classified as available-for-sale securities and are initially recognized at fair value. Unrealized gains and losses are recognized in accumulated other comprehensive income (loss), and "other than temporary" impairment losses are recognized in the condensed consolidation statements of comprehensive income (loss). Commissions paid at acquisition are included as part of the cost of the investment.

From July 9, 2015 through August 24, 2015, we purchased 2,250,000 shares of Depomed common stock, representing 3.75% of Depomed's common stock. The shares were acquired at a cost of $71.8 million.

As of September 30, 2015, we do not consider the decrease in fair value of the investment to be an "other than temporary" impairment. Unrealized losses of $29.4 million have been recorded in accumulated other comprehensive loss in the three and nine months ended September 30, 2015.

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 14, “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. 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 3.5% per annum (subject to a 1.00% 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%. Since drawing the full $400.0 million available in May 2015, our borrowings have been based on LIBOR. Since current LIBOR rates are below the 1.0% LIBOR floor, the interest rate on our borrowings has been 4.5% per annum. An increase in the LIBOR of 100 basis points above the 1.0% LIBOR floor would increase our interest expense 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 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. 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 products to pharmacies, hospitals and other customers. For the nine months ended September 30, 2015, our top five customers, McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen, American Specialty Pharmacy, Inc., and Rochester Drug Company accounted for approximately 82% of total consolidated gross sales. For the nine months ended September 30, 2014, our top five customers, AmerisourceBergen, Cardinal Health, Inc., McKesson Corporation, Mundipharma and Rochester Drug Company, accounted for approximately 90% of total consolidated

gross sales.

In addition, five customers, McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen, American Specialty Pharmacy, Inc. and Rochester Drug Company accounted for approximately 90% and 85% of our total outstanding accounts receivable balances at September 30, 2015 and December 31, 2014, respectively. Historically, we have not experienced any 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, 2015, the end of the period covered by this report.

Changes in Internal Control Over Financial Reporting. As discussed above, on September 19, 2014, a wholly-owned subsidiary of Horizon Pharma plc (formerly known as Vidara Therapeutics International Public Limited Company) merged with and into HPI, with HPI surviving the merger and becoming a wholly-owned subsidiary of Horizon Pharma plc. HPI is treated as the acquiring company in the Vidara Merger for accounting purposes, and the Vidara Merger was accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. Following the Vidara Merger, the financial statements of the current period reflect the financial position, results of operations and cash flows of Horizon Pharma plc. The results of operations of the acquired Vidara business are included in the results of operations of Horizon Pharma plc beginning on September 19, 2014. Also, as a result of the Vidara Merger, the internal control over financial reporting utilized by HPI prior to the Vidara Merger became the internal control over financial reporting of our company, and we are currently in the process of evaluating and integrating Vidara's historical internal controls over financial reporting with ours.

In addition, as discussed above, on May 7, 2015, we acquired Hyperion. The results of operations of the acquired Hyperion business are included in our results of operations beginning on May 7, 2015. We are currently in the process of evaluating and integrating Hyperion's historical internal controls over financial reporting with ours.

During the quarter ended September 30, 2015, other than continuing changes to our internal control processes resulting from the Vidara Merger and the Hyperion acquisition 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

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 affiliate 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 on-going patent infringement litigation. In accordance with legal requirements, the Company, Jagotec and Actavis FL have agreed to submit the Actavis Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The parties have agreed to file stipulations of dismissal with the court regarding the litigation. 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 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 in 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, they 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 November 13, 2014, the Company received a Paragraph IV Patent Certification from Actavis FL advising that Actavis FL had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Actavis FL has not advised the Company as to the timing or status of the FDA's review of its filing. On December 23, 2014, the Company filed suit in the United States District Court for the District of New Jersey against Actavis FL., Actavis, Inc., and Actavis plc (collectively "Actavis") seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges 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 generic versions of PENNSAID 2% prior to the expiration of the patents. The subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Actavis action.

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. And 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 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 the patents.

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 on-going patent infringement litigation. 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%.

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 in 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 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 the other parties.

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 before the expiration of 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 Limited and Lupin Pharmaceuticals Inc. (collectively, "Lupin"); (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, "Mylan"); and (iv) Watson Laboratories, Inc.—Florida, known as Actavis Laboratories FL, Inc. and Actavis Pharma, Inc. (collectively, "Actavis"). 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 Pozen 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 Pozen patents licensed to the Company under the amended and restated collaboration and license agreement for the United States with Pozen ("the Pozen license agreement").

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 and May 13, 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. On June 18, 2015, the Company amended the complaints to add a charge of infringement of U.S. Patent No. 8,865,190.

The cases asserting U.S. Patent Nos. 8,557,285 and 6,926,907 have been consolidated for discovery. The court has issued a claims construction order for these cases and has set a pretrial schedule, but has not yet set a trial date.

The cases asserting U.S. Patent Nos. 8,852,636, 8,858,996, and 8,865,190 have not been consolidated for discovery. The court has not issued a claims construction order or set a pretrial schedule.

The Company understands the cases arise from Paragraph IV 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 and February 9, 2015; the Actavis notice letters were dated March 29, 2013 November 5, 2013 and October 9, 2015; and the Anchen notice letter was dated September 16, 2011.

On February 24, 2015, Dr. Reddy's Laboratories, Inc. 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, Dr. Reddy's Laboratories, Inc.'s petition for inter partes review of U.S. Patent No. 8,557,285 was denied by the United States Patent and Trademark Office.

On May 21, 2015, the Coalition for Affordable Drugs VII LLC 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. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On June 5, 2015, the Coalition for Affordable Drugs VII LLC filed another Petition for IPR of U.S. Patent No. 8,858,996, one of the patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 7, 2015, the Coalition for Affordable Drugs VII LLC 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. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 12, 2015, the Coalition for Affordable Drugs VII LLC filed another Petition for IPR of U.S. Patent No. 8,945,621, one of the patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 19, 2015, Lupin filed Petitions for IPR of U.S. Patent Nos. 8,858,996, 8,852,636, and 8,865,190, all patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued decisions with regard to whether or not IPRs will be instituted.

On or about December 19, 2014, the Company filed a Notice of Opposition to a European patent, EP 2611457, to Roberto Testi, et al., covering compositions and methods for treating FA with interferon gamma, e.g., ACTIMMUNE. In the European Union, the grant of a patent may be opposed by one or more private 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 (the "Taro Settlement Agreement"), with Taro relating to our on-going patent infringement litigation. In accordance with legal requirements, the Horizon Subsidiaries and Taro have agreed to submit the Taro Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The Horizon Subsidiaries and Taro have also agreed to file stipulations of dismissal with the courts regarding the litigation. 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 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 in 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 Horizon'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 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%, they 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%. Lupin Limited has not advised the Company as to the timing or status of the FDA's review of its filing. On April 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Lupin, seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Lupin has infringed 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 the patents. The subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Lupin action.

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%.

The Company received from IGI Laboratories, Inc. ("IGI") 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 IGI had filed an ANDA with the FDA for a generic version of PENNSAID 2%. IGI has not advised the Company as to the timing or status of the FDA's review of its filing. On May 21, 2015, the Company filed suit in the United States District Court for the District of New Jersey against IGI seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that IGI 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 the patents. The subject patents are listed in the FDA's Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of IGI's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The court has not yet set a trial date for the IGI action.

On June 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against IGI 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 IGI 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 IGI 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%.

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%. Amneal has not advised the Company as to the timing or status of the FDA's review of its filing. 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 alleges 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 the patents. The

subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Amneal action.

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 March 17, 2014, Hyperion received notice from Par Pharmaceutical, Inc. ("Par") that it had filed an ANDA with the FDA seeking approval for a generic version of the Company's product 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, and U.S. Patent No. 8,642,012, titled "Methods of treatment using ammonia scavenging drugs," which expires in September 2030, are invalid and/or will not be infringed by Par's manufacture, use or sale of the product for which the ANDA was submitted. Par 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 phenylalkenoic 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. Hyperion filed suit in the United States District Court for the Eastern District of Texas, Marshall Division, against Par on April 23, 2014 seeking an injunction to prevent the approval of Par's ANDA and/or to prevent Par 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 that it had filed a Paragraph IV Patent Certification alleging that U.S. Patent No. 9,095,559 is invalid and/or will not be infringed by Par's manufacture, use or sale of the product for which the ANDA was submitted.

On April 29, 2015, Par filed petitions for IPR of the '215 patent and the '012 patent. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not IPRs will be instituted.

The Company received from Lupin Limited a Paragraph IV Patent Certification dated September 4, 2015 against Orange Book listed U.S. Patent Nos. 8,404,215 and 8,642,012 advising that Lupin had filed an ANDA with the FDA for a generic version of RAVICTI. 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 U.S. Patent Nos. 8,404,215, 8,642,012, and 9,095,559 by filing an ANDA seeking approval from the FDA to market generic versions of RAVICTI prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. The 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. The court has not yet set a trial date for the Lupin action.

On August 3, 2015, HPI filed a lawsuit in the Superior Court of the State of California, County of Santa Clara, naming as defendants Depomed and the members of its board of directors (the "Depomed Board"), Vicente J. Anido, Jr., Karen A. Dawes, Louis J. Lavigne, Jr., Samuel R. Saks, James A. Schoeneck, Peter D. Staple and David B. Zenoff. The lawsuit is captioned Horizon Pharma, Inc. v. Vicente J. Anido, Jr., et al., Case Number 1:15-cv-283835. The lawsuit alleges that the adoption by the Depomed Board of the Rights Agreement dated as of July 12, 2015 between Depomed and Continental Stock Transfer & Trust Company, as Rights Agent (the "Depomed Rights Agreement"), and Sections 2(b), 2(c), 2(d), and 5(d) of Depomed's Amended and Restated Bylaws, effective July 12, 2015 (the "Depomed Bylaws"), violates the General Corporation Law of the California Corporations Code, constitutes ultra vires acts and breaches the fiduciary duties of the members of the Depomed Board. The lawsuit seeks, among other things, an order (i) declaring that the Depomed Rights Agreement and Sections 2(b), 2(c), and 2(d) of the Depomed Bylaws are invalid under California law, (ii) declaring that the members of the Depomed Board breached their fiduciary duties by enacting the Depomed Rights Agreement and Sections 2(b), 2(c), 2(d), and 5(d) of the Depomed Bylaws, (iii) enjoining the members of the Depomed Board from relying on, implementing, applying or enforcing either the Depomed Rights Agreement or Sections 2(b), 2(c), 2(d), or 5(d) of the Depomed Bylaws, (iv) enjoining the members of the Depomed Board from taking any improper action designed to impede, or which has the effect of impeding, the proposed combination with Depomed or the Company's efforts to acquire control of Depomed and (v) compelling the members of the Depomed Board to redeem the Depomed Rights Agreement or to render it inapplicable to the Company. The Superior Court has calendared for November 5, 2015 a hearing on a preliminary injunction motion by HPI to enjoin enforcement of the Depomed Rights Agreement and Sections 2(b), 2(c) and 2(d) of the Depomed bylaws.

Also on August 3, 2015, Depomed filed a lawsuit in the Superior Court of the State of California, County of Santa Clara, against the Company. The lawsuit is captioned Depomed, Inc. v. Horizon Pharma plc, Case Number 1:15-cv-283834. The complaint asserts a claim for violation of the California Uniform Trade Secrets Act and breach of contract in connection with the Company's alleged use in pursuing the proposed combination with Depomed of information obtained pursuant to a confidentiality agreement entered into as part of the Company's consideration of a business arrangement with Janssen Pharmaceuticals Inc. relating to its U.S. rights to NUCYNTA®, which are now owned by Depomed. The complaint also alleges that the Company made fraudulent and materially misleading statements to Depomed's shareholders. The lawsuit seeks, among other relief, an injunction (i) to prevent the Company from continuing its allegedly improper and unlawful use of Depomed's confidential and trade secret data and (ii) to prevent the Company from continuing to make and failing to correct its allegedly false and misleading statements in connection with the proposed combination with Depomed. The Superior Court has calendared for November 5, 2015 a hearing on a preliminary injunction motion by Depomed.

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, 2014, as filed with the SEC.

Risks Related to Our Business and Industry

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

Our current products, and other products or product candidates that we may develop, acquire, or in-license may not attain market acceptance among physicians, patients, healthcare payors or the medical community. In the U.S. market, we began marketing DUEXIS in December 2011. We began commercial sales of RAYOS, which was approved by the U.S. Food and Drug Administration, or FDA, in July 2012, to a subset of rheumatologists in the fourth quarter of 2012 with the full launch to the majority of U.S. rheumatologists and key primary care physicians in late January 2013. VIMOVO was launched in the U.S. market in the fourth quarter of 2010 by AstraZeneca AB, or AstraZeneca, under its license from Pozen Inc., or Pozen. Following our acquisition of the U.S. rights to VIMOVO in November 2013, we began marketing VIMOVO in the first quarter of 2014. ACTIMMUNE was originally launched in the U.S. market in March 1991 by Genentech Inc., or Genentech, and in June 2012, Vidara Therapeutics International plc, or Vidara, acquired the intellectual property rights and certain assets related to the ACTIMMUNE product line. In September 2014, our business was combined with Vidara, and as a result we assumed the commercialization of ACTIMMUNE. In October 2014, we entered into an asset purchase agreement and ancillary agreements with Nuvo Research, Inc., or Nuvo, to acquire the U.S. rights to PENNSAID 2%, and we began commercializing PENNSAID 2% in the United States in January 2015. With respect to DUEXIS, we have only received marketing approval in the United Kingdom, or the U.K., thus far, and we do not expect the opportunity in the U.K. to be material to our business given the current state of the market in Europe for pain and inflammation products and the revenue being generated by existing branded non–steroidal anti-inflammatory drugs, or NSAIDs, in Europe. There have been no sales of DUEXIS in the U.K. thus far. RAVICTI was launched in the United States by Hyperion Therapeutics, Inc., or Hyperion, in the first quarter of 2013, and BUPHENYL was originally launched in 1996 prior to being acquired by Hyperion. In May 2015, we acquired Hyperion and assumed the commercialization of RAVICTI and BUPHENYL. Neither product was marketed by us prior to that time. We believe that the degree of market acceptance and our ability to generate revenues from our products will depend on a number of factors, including:

- timing of market introduction of our products as well as competitive products;
- efficacy and safety of our products;
- continued projected growth of the markets in which our products compete;
- prevalence and severity of any side effects;
- if and when we are able to obtain regulatory approvals for additional indications for our products;
- acceptance by patients, primary care specialists and key specialists, including rheumatologists, orthopedic surgeons, pain specialists 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 payors;
- the performance of third-party distribution partners, over which we have limited control;
-

potential or perceived advantages or disadvantages of our products 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 products, both in absolute terms and relative to alternative treatments;
- impact of past and limitation of future product price increases;
- our ability to maintain a continuous supply of product for commercial sale;
- the effect of current and future healthcare laws; and
- product labeling or product insert requirements of the 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 NSAIDs. We believe this is due in part to a lack of awareness among physicians prescribing NSAIDs of 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%, 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 payors. 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. If our current products or any other product that we may seek approval for, acquire or in-license 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 current business plan is highly dependent upon our ability to successfully execute on our sales and marketing strategy for the commercialization of our products in the United States. If we are unable to successfully execute on our sales and marketing strategy, we may not be able to generate significant product revenues or execute on our business plan.*

Our strategy is to build a fully-integrated U.S.-focused biopharmaceutical company to successfully execute the commercialization of our products in the U.S. market. We may not be able to successfully commercialize our products in the United States. Prior to our commercial launch of DUEXIS in the United States in December 2011, we did not have any experience commercializing pharmaceutical products on our own. LODOTRA was commercially launched in Europe by our exclusive distribution partners Merck Serono GmbH and Mundipharma. In order to commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Although we have expanded our sales force to approximately 402 sales representatives, consisting of 349 primary care sales representatives, 44 specialty sales representatives and 9 orphan disease 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 products and any additional products we may acquire or in-license 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 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 and BUPHENYL with respect to generic brands and could face similar challenges with respect to PENNSAID 2% due to the availability of generic versions of PENNSAID 1.5%. 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 BUPHENYL, DUEXIS, PENNSAID 2%, RAYOS and VIMOVO prescriptions 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 products, we may receive less revenue than if we commercialized these products 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 products and product candidates and execute on our business plan.

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 product, in the absence of specific instructions from the prescribing physician. Because our products (other than BUPHENYL) do not currently have FDA-approved generic equivalents in the United States, we do not believe our products should be subject to mandatory generic substitution laws. However we understand that some pharmacies and payors may attempt to reduce costs by obtaining physician authorization to switch prescriptions for DUEXIS or VIMOVO to prescriptions for multiple generic products with similar active pharmaceutical ingredients, or APIs. Accordingly, a key part of our commercial strategy is to offer physicians to have their patients fill their prescriptions through pharmacies participating in our Prescriptions Made Easy program, or PME. Through the PME program, financial assistance may be available to reduce eligible patients' out-of-pocket costs for prescriptions filled. Because of this assistance, the patients' out-of-pocket cost for our products when dispensed through the PME program may be significantly lower than such costs when our products are dispensed outside of the PME program.

We expect that continued utilization of our patient support programs, including PME, by patients will be important to our ability to provide access for more patients to our products as pressure increases from healthcare payors and pharmacy benefit managers, or PBMs, to use less expensive generics or over the counter brands instead of branded products. For example, two of the largest PBMs, which we estimate to currently control approximately 20% to 30% of prescriptions for DUEXIS and VIMOVO, placed DUEXIS and VIMOVO on their exclusion lists beginning in 2015. Additional healthcare plans, including those that contract with these PBMs but use different formularies, may also choose to exclude our products from their formularies or restrict coverage to situations where a generic or over-the-counter product has been tried first. To the extent physicians do not direct prescriptions currently filled through traditional pharmacies, including those associated with or controlled by these PBMs, to our PME program, we may experience a significant decline in DUEXIS, VIMOVO and PENNSAID 2% prescriptions as a result of formulary exclusions.

There has been recent negative publicity regarding the use of specialty pharmacies and drug pricing. Our products are distributed by both retail and specialty pharmacies. A key part of our commercial strategy for our primary care and specialty business units is to offer physicians the opportunity to have their patients fill prescriptions through pharmacies who participate in the PME program. This program is not involved in the prescribing of medicines, and is solely to assist in ensuring that when a physician determines one of our medicines offers a potential clinical benefit to their patient and they prescribe one for an eligible patient, financial assistance may be available to reduce the patient's out-of-pocket costs. In the first nine months of 2015, this resulted in 96 percent of commercial patients having co-pay amounts of $10 or less when filling prescriptions for our products through PME. In addition, the aggregate commercial value of our patient support programs for the nine months ended September 30, 2015 was approximately $670 million. All pharmacies that fill prescriptions for our medicines are fully independent, including those that participate in the PME program, we do not own or possess any option to purchase an ownership stake in any pharmacy that distributes our products, and our relationship with each pharmacy is non-exclusive and arm's length. All of our sales are processed through pharmacies independent of the Company.

Pharmacies that dispense our products 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. 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 products and collect reimbursement from MCOs for such products.

Our ability to increase utilization of our PME program will depend on physician and patient awareness and comfort with the program, and we have limited ability to influence whether physicians use our PME program to prescribe our products or whether patients will agree to receive our products through the PME program. In addition, the PME program is not available to federal health care program (such as Medicare and Medicaid) beneficiaries. If we are unable to increase adoption of our PME program for filling prescriptions of our products, our ability to maintain or increase prescriptions for our products will be impaired. In addition, we depend on a limited number of pharmacies participating in PME to fulfill patient prescriptions under the PME program. If these PME participating pharmacies are unable to process and fulfill the volume of patient prescriptions directed to them under the PME program, our ability to maintain or increase prescriptions for our products will be impaired. The commercialization of our products and our operating results could be affected should any of the PME participating pharmacies choose not to continue participation in our PME program or by any adverse events at any of those PME participating pharmacies. In addition, the PME 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. To the extent the PME program is found to be inconsistent with applicable laws, we may be required to restructure or discontinue such program, or be subject to other significant penalties.

If we are unable to successfully implement our commercial plans and facilitate adoption by patients and physicians of any approved products through our sales, marketing and commercialization efforts, or if our partners fail to

successfully commercialize our products, then we will not be able to generate sustainable revenues from product sales which will have a material adverse effect on our business and prospects.

Our future prospects are highly dependent on the success of our current products, and we may not be able to successfully commercialize these products. 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 products. Our ability to generate significant product revenues and to achieve commercial success in the near-term will initially depend almost entirely on our ability to successfully commercialize these products in the United States. DUEXIS has been approved for marketing in the U.K. but is not approved in any other countries in Europe and therefore, DUEXIS may not be commercialized to any significant extent outside of the United States. We do not expect the opportunity in Europe to be material to our business given the current state of the market in Europe for pain products and the revenue being generated by existing branded NSAIDs in Europe. Following our acquisition of the U.S. rights to VIMOVO in November 2013 and PENNSAID 2% in October 2014, our strategy has included bringing both products' pricing in-line with DUEXIS, thereby significantly increasing the value we realize per prescription, and also increasing sales and marketing support to drive growth in prescriptions. We cannot guarantee that this strategy will continue to be effective generally, due to negative reactions to price increases or otherwise. Our strategy for RAYOS is to solely focus on the rheumatology indications approved for RAYOS where our Phase 3 clinical trial data supports our commercial plans. We initially launched RAYOS in the United States to a subset of rheumatologists in the fourth quarter of 2012, and the full launch to the majority of U.S. rheumatologists and key primary care physicians occurred in late January 2013. Our strategy with respect to ACTIMMUNE includes pricing increases, pursuing label expansion for additional indications, such as Friedreich's ataxia, or FA, and possible expansions of our sales force, 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. Although LODOTRA is approved for marketing in more than 35 countries outside the United States, to date it has only been marketed in a limited number of countries. While we anticipate that LODOTRA will be marketed in additional countries as our distribution partner, Mundipharma, formulates its reimbursement strategy, the ability to market LODOTRA in additional countries will depend on Mundipharma's ability to obtain reimbursement approvals in these countries.

Our strategy with respect to RAVICTI includes accelerating the transition of UCD patients from BUPHENYL or generic equivalents to RAVICTI and increasing the diagnosis of UCD and treatment of untreated UCD patients through patient and physician outreach. Part of our success in our strategy will be obtaining favorable results from an on-going study of the use of RAVICTI to treat UCD in patients less than two years of age, the timely submission of a supplemental new drug application, or NDA, and approval of RAVICTI for the treatment in UCD in patients less than two years of age, and we cannot guarantee that any of these events will occur on our anticipated timeline or at all. In addition, RAVICTI is currently only approved for marketing in the United States, while the CHMP of the EMA, recently adopted a positive opinion at its plenary monthly meeting in September recommending a centralized marketing authorization for RAVICTI for use as an adjunctive therapy for chronic management of adult and pediatric UCD patients greater than two months of age, we cannot guarantee that the European Commission will ultimately grant a centralized marketing authorization. If required regulatory approvals in international markets are never obtained, are delayed or are not maintained, the market potential of RAVICTI will be limited. Additionally, if approval to market RAVICTI in Europe is not obtained prior to February 2016, when the RAVICTI composition of matter patent expires in European jurisdictions in which it is validated, we will not be eligible to apply to extend the patent's term, and we will have to rely on maintaining orphan designation to ensure marketing exclusivity in Europe. We cannot guarantee that we can maintain orphan designation for RAVICTI in Europe as we must demonstrate that the product provides "significant benefit" in those UCD subtypes for which AMMONAPS® is approved.

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

We rely on 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 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, our current ex-U.S. distributors for BUPHENYL, or any other third-party with any future commercialization rights to any of our products or product candidates fail to adequately commercialize those products or product candidates because they lack adequate financial or other resources, decide to focus on other initiatives or otherwise, our ability to successfully commercialize our products or product 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 products are subject to extensive regulation, and we may not obtain additional regulatory approvals for our products.*

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution and other possible activities relating to our products and our product 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 product 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 product 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, or MAA, 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 product candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product 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 product candidate for many reasons, including because they:

- may not deem a product 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 product 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 product 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 product 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, product candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the product 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 product candidates. We cannot predict when or whether regulatory approval will be obtained for any product candidate we develop.

While we anticipate that LODOTRA will be marketed in additional countries as Mundipharma formulates its reimbursement strategy, the ability to market LODOTRA in additional countries will depend on Mundipharma's ability to obtain regulatory and reimbursement approvals in these countries. Similarly, our ability to market DUEXIS outside of the United States will depend on obtaining regulatory and reimbursement approval in any country where DUEXIS

may be marketed. However, certain countries have a very difficult reimbursement environment and we may not obtain reimbursement approval in all countries where DUEXIS may be marketed, or we may obtain reimbursement approval at a level that would make marketing DUEXIS in certain countries not viable.

RAVICTI is currently only approved for marketing in the United States and our ability to expand our market potential will depend in part on our ability to obtain additional marketing approvals outside the United States. This is particularly true due to our decision to not pursue approval in the United States for the treatment of hepatic encephalopathy, or HE. On September 25, 2015, the CHMP of the EMA adopted a positive opinion at its plenary monthly meeting in September recommending a centralized marketing authorization for RAVICTI for use as an adjunctive therapy for chronic management of adult and pediatric UCD patients greater than two months of age. The adopted positive opinion will be considered by the European Commission for a binding decision to be issued for the granting of a centralized marketing authorization, expected to be received within 60 to 90 days from the date of adoption of the opinion. Hyperion submitted a New Drug Submission to Health Canada, or HC, for approval to market RAVICTI in Canada. However, in January 2015, Lucane Pharma, or Lucane, announced that it had received approval from HC to market its taste-masked NaPBA granules in Canada. It is our understanding that in Canada only the first phenylbutyrate-containing product approved for any indication receives “data protection” which is similar to “orphan drug exclusivity” in the United States. Hyperion was notified by HC that RAVICTI is not eligible for data protection. We have appealed this decision not to grant data protection to RAVICTI and the appeal is currently scheduled for hearing on December 8, 2015. If we cannot successfully appeal this decision to obtain data protection, the application for marketing approval in Canada may be withdrawn. Regardless, we cannot be assured that the applications to market RAVICTI in Europe and Canada will be approved nor can we be certain of the timelines for regulatory decisions to be made. If we are unable to obtain approvals for RAVICTI outside the United States or determine that commercializing RAVICTI outside the United States is not economically viable, the market potential of RAVICTI will be limited.

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.*

Following our acquisition of Vidara in September 2014, our acquisition of the U.S. rights to PENNSAID 2% from Nuvo in October 2014 and our acquisition of Hyperion in May 2015, we have seven products approved in the United States, one product with broad approval for commercial sale in Europe, another product approved only for commercial sale in the U.K. thus far and one product which is approved in additional territories, including Europe. RAYOS/LODOTRA has been approved in the United States and over 35 other countries, including Australia, Colombia and select countries within Europe and Asia. However, we have a limited history of marketing LODOTRA through our distribution partners, and LODOTRA is not yet marketed in all of the countries where it has been approved. We began the commercial sale of DUEXIS in the United States in December 2011, the commercial sale of RAYOS in the United States in the fourth quarter of 2012, the commercial sale of VIMOVO in the United States in the first quarter of 2014 and the commercial sale of ACTIMMUNE as a combined company with Vidara in September 2014. We began commercializing PENNSAID 2% in the United States in January 2015 and began commercializing RAVICTI and BUPHENYL in May 2015. 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 PENNSAID 2% and VIMOVO and, as a combined company, ACTIMMUNE, BUPHENYL and RAVICTI, 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 our commercial organization with Hyperion’s, or to commercialize VIMOVO, ACTIMMUNE, PENNSAID 2%, BUPHENYL and RAVICTI within our organization or not realize the benefits we expect to derive from our recent acquisitions.

We have U.S. rights to ACTIMMUNE, PENNSAID 2% and VIMOVO but have no control over the activities of Boehringer Ingelheim to commercialize ACTIMMUNE outside the United States, Canada and Japan, AstraZeneca to commercialize VIMOVO outside of the United States or Nuvo or its licensees to commercialize PENNSAID 2% outside the United States, which could adversely impact commercialization of ACTIMMUNE, PENNSAID 2% and VIMOVO in the United States.*

Boehringer Ingelheim has rights to commercialize ACTIMMUNE outside the United States, Canada and Japan, and 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. Similarly, 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's activities with respect to ACTIMMUE outside the United States, Canada and Japan, over AstraZeneca's activities with respect to VIMOVO outside of the United States 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, PENNSAID 2% and VIMOVO in the United States. For example, Nuvo or its assignees or AstraZeneca or its assignees can make statements or use promotional materials with respect to PENNSAID 2% or VIMOVO, respectively, outside of the United States that are inconsistent with our positioning of the products in the United States, and could sell PENNSAID 2% or VIMOVO, 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, product recalls or safety issues with ACTIMMUNE, PENNSAID 2% or VIMOVO outside the United States, even if not related to the commercial product 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, PENNSAID 2% and VIMOVO. We also rely on Boehringer Ingelheim, Nuvo and AstraZeneca or their assignees to provide us with timely and accurate safety information regarding the use of ACTIMMUNE, PENNSAID 2% or VIMOVO, respectively, outside of the United States, (and outside of Canada and Japan with regards to Boehringer Ingelheim) 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 products, and we currently intend to rely on third parties to manufacture commercial supplies of any other approved products. The commercialization of any of our products could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of product 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 products and product 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 sanofi-aventis U.S. LLC, or sanofi-aventis U.S., operating through Valeant Pharmaceuticals International, Inc., or Valeant, our manufacturing partner located in Laval, Canada for production of DUEXIS, and Jagotec AG, or Jagotec, a wholly-owned subsidiary of SkyePharma PLC, or SkyePharma, located in Lyon, France, for production of RAYOS/LODOTRA. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to Aenova France SAS, or Aenova. As such, Aenova is now a subcontractor for Jagotec for the manufacture of RAYOS/LODOTRA, with our consent. Sanofi Winthrop Industrie in France has been qualified as a backup manufacturer for DUEXIS. Bayer Pharma AG, or Bayer, in Germany has been qualified as a backup manufacturer for RAYOS/LODOTRA. In December 2011, Valeant acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. We purchase the primary active ingredients for DUEXIS from BASF Corporation in Bishop, Texas and Dr. Reddy's in India, and the primary active ingredient for RAYOS/ LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and Sanofi Chimie in France.

In connection with our acquisition of the U.S. rights to VIMOVO, we entered into a long-term master manufacturing services and product agreement with Patheon Pharmaceuticals Inc., or Patheon, for the supply of finished VIMOVO product. We have entered into long-term supply agreements with Divis Laboratories Limited and Minakem Holding SAS for the supply of the APIs of VIMOVO. 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.

With respect to ACTIMMUNE, we rely on an exclusive supply agreement with Boehringer Ingelheim RCV GmbH & Co. KG, or Boehringer Ingelheim, for manufacturing and supply. However, Boehringer Ingelheim also manufactures interferon gamma-1 b to supply its own commercial needs in its licensed territory, and this may lead to capacity allocation issues and supply constraints to our company. Furthermore, we do not have a substitute supplier for ACTIMMUNE and the process of identifying a substitute supplier and getting that supplier approved by the applicable regulatory authorities for manufacture and packaging of ACTIMMUNE can be a lengthy and costly process. 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.

With respect to PENNSAID 2%, we rely on an exclusive supply agreement with Nuvo for manufacturing and supply. If Nuvo licenses its rights to PENNSAID 2% to commercialization partners outside of the United States, it is possible that Nuvo would also agree to manufacture and supply PENNSAID 2% for those partners. In that case, we would have no guarantee that fulfilling demand for PENNSAID 2% in territories outside the United States would not impair Nuvo's ability to supply us with our requested quantities of PENNSAID 2% in the United States. In addition, while our supply agreement with Nuvo provides for the qualification of additional manufacturing sites for PENNSAID 2%, we and Nuvo may not be successful in finding alternative manufacturers to supply PENNSAID 2% or agreeing to commercially reasonable terms with alternate suppliers. A key excipient used in PENNSAID 2% as a penetration enhancer is dimethyl sulfoxide, or DMSO. We and Nuvo 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.

With respect to RAVICTI and BUPHENYL, we rely on third parties for the manufacture of clinical and commercial supplies. We have bulk drug substance for the production of clinical and commercial supplies of RAVICTI manufactured for us by Helsinn Advanced Synthesis SA (Switzerland) and DPx Fine Chemicals Austria GmbH on a purchase order basis. We have bulk drug substance for the production of clinical and commercial supplies of BUPHENYL manufactured for us by CU Chemie Uetikon GmbH (Germany).

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. 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 products 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 products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products. To the extent any third-party manufacturers that we engage with respect to our products 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 products prior to our sale of any product using these facilities.

Although we have entered into supply agreements for the manufacture of our products, 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., operating through Valeant, 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, so long as such notice is given after the third anniversary of the first commercial sale of DUEXIS. Under our master manufacturing services and product agreement with Patheon for finished VIMOVO product, 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 product 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, 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, in such an event and we would have to qualify a new back-up manufacturer. The initial term of our supply agreement with Nuvo for PENNSAID 2% is through December 31, 2022, 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 Pharmaceutics International, Inc. 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. for RAVICTI runs until February 1, 2016, with provision for 12 monthly auto renewals thereafter, unless 6 months' written notice is provided by either party. As neither party has given 6 months' notice this contract will auto-renew until February 1, 2017. The agreement may be terminated earlier, on 30 days' notice, in case of breach by either party. We rely on safety stock to mitigate the risk of our current suppliers electing to cease producing bulk drug product 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 products for distribution. Consequently, we have entered into an agreement with Temmler Werke GmbH, or Temmler, for packaging of RAYOS/LODOTRA in certain European countries and in the United States, as well as any additional countries as may be agreed to by the parties. At the end of 2012, Temmler was acquired by the Aenova Group. In December 2013, Temmler provided us notice of termination under this agreement. Therefore, subject to early termination, this agreement will terminate on December 21, 2015. Under our master manufacturing services agreement with Patheon, we have entered into a product agreement for packaging of RAYOS/LODOTRA after our agreement with Temmler is terminated. Valeant 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 product 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 is obligated to supply final, packaged PENNSAID 2% to us, in each case under exclusive supply agreements. We have clinical and commercial supplies of BUPHENYL finished product manufactured for us by Pharmaceutics International, Inc. on a purchase order basis. We have clinical and commercial supplies of RAVICTI finished drug product manufactured by Lyne Laboratories, Inc. under a commercial supply agreement and have an agreement in place with Halo Pharmaceutical, Inc. to serve as the primary finished drug product supplier for RAVICTI in the European Union and as a secondary finished drug product supplier for the rest of the world.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products 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 product, 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 drug products or in the manufacturing facilities in which our products 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 products 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 products in the United States or provide any product candidates to patients in clinical trials would be jeopardized.

Any delay or interruption in our ability to meet commercial demand for our products will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. 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 products or product 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 acquisition of the U.S. rights to VIMOVO in November 2013, our acquisition of Vidara in September 2014, our acquisition of the U.S. rights to PENNSAID 2% in October 2014 and our acquisition of Hyperion in May 2015, and we may experience difficulties in managing this growth as well as potential additional growth in connection with future product acquisitions or company acquisitions.*

As of December 31, 2010, we employed approximately 40 full-time employees as a consolidated entity. In anticipation of the commercial launch of DUEXIS, we hired approximately 80 sales representatives during the period from September 2011 through October 2011. Recently, we further increased the size of our sales force in connection

with our acquisitions of PENNSAID 2% and Hyperion to a total of approximately 402 sales representatives. As of September 30, 2015 and December 31, 2014, we employed approximately 710 and 535 full-time employees, respectively, as a consolidated entity. 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 products, 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 of Vidara, PENNSAID 2% and Hyperion. 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 products;
- 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 products and product 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 Vidara's business is subject to numerous uncertainties and risks and will 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 has resulted in many changes, including significant changes in the corporate business and legal entity structure, the integration of Vidara and its personnel with us, and changes in systems. We are currently undertaking numerous complex transition activities, and we may encounter unexpected difficulties or incur unexpected costs, including:

- difficulties in achieving growth prospects from combining Vidara's business 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 customers and obtaining new customers; 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 Vidara successfully or on a timely basis, 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.

Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities and towards 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 may fail to realize all of the anticipated benefits of the acquisition of Hyperion or those benefits may take longer to realize than expected. We may also encounter significant difficulties in integrating Hyperion's business into our operations.*

Our ability to realize the anticipated benefits of the acquisition of Hyperion will depend, to a large extent, on our ability to integrate Hyperion's business into our existing operations. The combination of two independent businesses is a complex, costly and time-consuming process that will require significant management attention and resources. The integration process may disrupt the businesses and, if implemented ineffectively, would limit the expected benefits to us of the acquisition of Hyperion. The failure to meet the challenges involved in integrating the two businesses and to realize the anticipated benefits of the acquisition of Hyperion could cause an interruption of, or a loss of momentum in, the activities of the combined company and could adversely affect the results of operations of the combined company.

In addition, the overall integration of the businesses may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customer and other business relationships, and diversion of management's attention. The difficulties of combining the operations of the companies include, among others:

- the diversion of management's attention to integration matters;
- difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects from the combination;
- difficulties in the integration of operations and systems;

- conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the two companies;
- difficulties in the assimilation of employees and corporate cultures;
- potential unknown liabilities, adverse consequences and unforeseen increased expenses associated with the acquisition of Hyperion; and
- challenges in attracting and retaining key personnel.

Many of these factors will be outside of our control and any one of these factors could result in increased costs, decreases in the amount of expected revenues and additional diversion of management's time and energy, which could materially adversely impact the business, financial condition and results of operations of the combined company. In addition, even if the operations of our business and Hyperion's business are integrated successfully, the full benefits of the acquisition of Hyperion may not be realized, including the synergies, cost savings, revenue growth or other benefits that are expected. These benefits may not be achieved within the anticipated time frame, or at all. Further, additional unanticipated costs may be incurred in the integration of our business with Hyperion's business. All of these factors could cause dilution to our earnings per share, decrease or delay the expected accretive effect of the acquisition of Hyperion, and negatively impact the price of our ordinary shares. As a result, we cannot provide any assurance that the acquisition of Hyperion will result in the realization of the full benefits anticipated from the transactions.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize our products in the United States will be harmed.*

As DUEXIS and RAYOS were not fully commercially launched in the United States until December 2011 and January 2013, respectively, and we did not begin commercializing VIMOVO and PENNSAID 2% in the United States until the first quarter of 2014 and 2015, respectively, the members of our sales force have limited experience promoting our products. In addition, while the members of our sales force promoting ACTIMMUNE were previously promoting the product prior to our acquisition of Vidara, we have limited experience marketing ACTIMMUNE under our commercial organization. Likewise, while we have retained the substantial majority of Hyperion's sales force promoting RAVICTI and BUPHENYL, we may not be successful in continuing to retain these employees and we otherwise have limited experience marketing these products 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 products. In addition, we must train our sales force to ensure that a consistent and appropriate message about our products is being delivered to our potential customers. Our sales representatives may also experience challenges promoting multiple products when we call on physicians and their office staff. This is particularly true with respect to DUEXIS and VIMOVO, since they are approved for similar indications and prescribed to similar patients. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire, requiring us to train new sales representatives. As a result of the managed care environment and pharmacies switching patient's prescriptions to a generic or over the counter brand, we have had to adjust the profile of the sales representatives we hire from the traditional pharmaceutical representative to a representative with business to business experience that is focused on the total office call in order to protect the prescription the physician has written and ensure the patient receives what their doctor ordered. 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 potential customers about the benefits of our products and their proper administration and label indication, as well as our PME program, our efforts to successfully commercialize our products could be put in jeopardy, which could have a material adverse effect on our financial condition, share price and operations.

We face significant competition from other biotechnology and pharmaceutical companies, including those marketing generic products 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, products that are more effective and/or less costly than our products.

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DUEXIS and VIMOVO face competition from Celebrex®, marketed by Pfizer, and several other branded NSAIDs. 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 PENNSAID 1.5% 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 product, 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 we are unsuccessful in convincing physicians to complete prescriptions through our PME 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 PENNSAID 1.5% 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 product candidates that contain ibuprofen and famotidine in combination or naproxen and esomeprazole in combination, while not currently known to us, may be developed and compete with DUEXIS or VIMOVO, respectively, in the future.

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an Abbreviated New Drug Application, or ANDA, with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. We subsequently filed patent infringement lawsuits against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., or collectively Par, relating to the ANDA and Par's intention to market a generic version of DUEXIS. 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 relating to the patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both us and Par of all claims that were or could have been asserted in the litigation and that arise out of the specific patent issues that were the subject of the litigation, including all resulting damages or other remedies.

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. The License covers all patents owned or controlled by us during the term of the Par license agreement that would, absent the License, be infringed by the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States. Unless terminated sooner pursuant to the terms of the Par license agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in 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.

Under the Par license agreement, we also agreed, on our behalf and on behalf of our affiliates, not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by us during the term of the Par license agreement based on the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States.

The Par license agreement may be terminated by us if Par commits a material breach of the agreement that is not cured or curable within 30 days after we provide notice of the breach. We may also terminate the Par license agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the Par license agreement will terminate automatically upon termination of the Par settlement agreement.

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

On October 1, 2015, we, as well as Jagotec, entered into a License and Settlement Agreement, or the Actavis Settlement Agreement, with Actavis FL, relating to our and Jagotec's on-going patent infringement litigation. In accordance with legal requirements, we, Jagotec and Actavis FL have agreed to submit the Actavis Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The parties have agreed to file stipulations of dismissal with the court regarding the litigation. 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, 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 in 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.

We 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 us 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 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 November 13, 2014, we received a Paragraph IV Patent Certification from Actavis FL advising that Actavis FL had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Watson has not advised us as to the timing or status of the FDA's review of its filing. On December 23, 2014, we filed suit in the United States District Court for the District of New Jersey against Actavis FL, Actavis, Inc., and Actavis plc (collectively "Actavis") seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges 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 generic versions of PENNSAID 2% prior to the expiration of the patents. The subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Actavis action.

On June 30, 2015, we 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, we 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. And on September 17, 2015, we 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 December 2, 2014, we 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, or Paddock,

advising that Paddock had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On January 9, 2015, we 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, we 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 the patents.

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, or collectively Perrigo, relating to our on-going patent infringement litigation. The Perrigo settlement agreement provides for a full settlement and release by both us 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%.

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 in 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.

Under the Perrigo settlement agreement, we also agreed not to sue or assert any claim against Perrigo for infringement of any patent or patent application owned or controlled by us during the term of 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%, we may be required to supply Perrigo PENNSAID 2% 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.

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 before the expiration of 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., or collectively Dr. Reddy's; (ii) Lupin Limited and Lupin Pharmaceuticals Inc., or collectively Lupin; (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc., or collectively Mylan; and (iv) Watson and Actavis Pharma, Inc., or collectively Actavis. Patent litigation in the United States District Court for the District of New Jersey against a fifth generic company, Anchen Pharmaceuticals Inc., or Anchen, was dismissed on June 9, 2014 after Anchen recertified under Paragraph III. We understand 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 Pozen VIMOVO patents, which are still the subject of patent litigations. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the amended and restated collaboration and license agreement for the United States with Pozen, or the Pozen license agreement.

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 and May 13, 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. On June 18, 2015, we amended the complaint to add a charge of infringement of U.S. Patent No. 8,865,190.

The cases asserting U.S. Patent Nos. 8,557,285 and 6,926,907 have been consolidated for discovery. The court has issued a claims construction order for these cases and has set a pretrial schedule, but has not yet set a trial date.

The cases asserting U.S. Patent Nos. 8,852,636, 8,858,996, and 8,865,190 have not been consolidated for discovery. The court has not issued a claims construction order or set a pretrial schedule.

We understand the cases arise from Paragraph IV 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. We

understand 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 and February 9, 2015; the Actavis notice letters were dated March 29, 2013, November 5, 2013 and October 9, 2015; and the Anchen notice letter was dated September 16, 2011.

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, Dr. Reddy's Laboratories, Inc.'s petition for inter partes review of U.S. Patent No. 8,557,285 was denied by the United States Patent and Trademark Office.

On May 21, 2015, the Coalition for Affordable Drugs VII LLC 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. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On June 5, 2015, the Coalition for Affordable Drugs VII LLC filed another Petition for IPR of U.S. Patent No. 8,858,996, one of the patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 7, 2015, the Coalition for Affordable Drugs VII LLC 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. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 12, 2015, the Coalition for Affordable Drugs VII LLC filed another Petition for IPR of U.S. Patent No. 8,945,621, one of the patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 19, 2015, Lupin filed Petitions for IPR of U.S. Patent Nos. 8,858,996, 8,852,636, and 8,865,190, all patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued decisions with regard to whether IPRs will be instituted.

On or about December 19, 2014, we filed a Notice of Opposition to a European patent, EP 2611457, to Roberto Testi, et al., covering compositions and methods for treating FA with interferon gamma, e.g., ACTIMMUNE. In the European Union, or EU, the grant of a patent may be opposed by one or more private parties.

On February 2, 2015, we 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., or collectively Taro, advising that Taro had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On March 13, 2015, we 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, the Horizon Subsidiaries entered into a settlement and license agreement, or the Taro Settlement Agreement, with Taro relating to our on-going patent infringement litigation. In accordance with legal requirements, the Horizon Subsidiaries and Taro have agreed to submit the Taro Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The Horizon Subsidiaries and Taro have also agreed to file stipulations of dismissal with the courts regarding the litigation. 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 in 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 our 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 us during the term of 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%, they 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, we 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%. Lupin Limited has not advised us as to the timing or status of the FDA's review of its filing. On April 30, 2015, we 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 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 the patents. The subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Lupin action.

On June 30, 2015, we 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, we 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, we 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%.

We received from IGI Laboratories, Inc., or IGI, 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 IGI had filed an ANDA with the FDA for a generic version of PENNSAID 2%. IGI has not advised us as to the timing or status of the FDA's review of its filing. On May 21, 2015, we filed suit in the United States District Court for the District of New Jersey against IGI seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that IGI 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 the patents. The subject patents are listed in the FDA's Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of IGI's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The court has not yet set a trial date for the IGI action.

On June 30, 2015, we filed suit in the United States District Court for the District of New Jersey against IGI for patent infringement of U.S. Patent No. 9,066,913. On August 11, 2015, we filed suit in the United States District Court for the District of New Jersey against IGI 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 IGI 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%.

We received from Amneal Pharmaceuticals LLC, or 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%. Amneal has not advised us as to the timing or status of the FDA's review of its filing. On May 15, 2015, we 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 alleges 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 the patents. The subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Amneal action.

On June 30, 2015, we 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, we 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, we 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 March 17, 2014, Hyperion received notice from Par Pharmaceutical, Inc., or Par, that it had filed an ANDA with the FDA seeking approval for a generic version of our product 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, and U.S. Patent No. 8,642,012, titled "Methods of treatment using ammonia scavenging drugs," which expires in September 2030, are invalid and/or

will not be infringed by Par's manufacture, use or sale of the product for which the ANDA was submitted. Par did not challenge the validity, enforceability, or infringement of our primary composition of matter patent for RAVICTI, U.S. Patent No. 5,968,979 titled "Triglycerides and ethyl esters of phenylalkanoic acid and phenylalkenoic 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. Hyperion filed suit in the United States District Court for the Eastern District of Texas, Marshall Division, against Par on April 23, 2014 and we have taken over and are responsible for this patent litigation. On September 15, 2015, we received notice from Par that it had filed a Paragraph IV Patent Certification alleging that U.S. Patent No. 9,095,559 is invalid and/or will not be infringed by Par's manufacture, use or sale of the product for which the ANDA was submitted.

On April 29, 2015, Par filed petitions for IPR of the '215 patent and the '012 patent. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not IPRs will be instituted.

We received from Lupin Limited a Paragraph IV Patent Certification dated September 4, 2015 against Orange Book listed U.S. Patent Nos. 8,404,215 and 8,642,012 advising that Lupin had filed an ANDA with the FDA for a generic version of RAVICTI. Lupin has not advised the Company as to the timing or status of the FDA's review of its filing. On October 19, 2015, we 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 U.S. Patent Nos. 8,404,215, 8,642,012, and 9,095,559 by filing an ANDA seeking approval from the FDA to market generic versions of RAVICTI prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. The 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. The court has not yet set a trial date for the Lupin action.

If we are unsuccessful in any of the on-going patent litigations, we will likely face generic competition with respect to VIMOVO, PENNSAID 2% and/or RAYOS and our sales of VIMOVO, PENNSAID 2% and/or RAYOS will be substantially harmed. If Par Pharmaceutical, Inc. were to prevail in the patent litigation with respect to RAVICTI and its ANDA were to receive FDA approval, 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 product currently approved by the FDA specifically for the treatment for CGD and SMO. While there are additional or alternative approaches used to treat patients with CGD and SMO, there are currently no products 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. 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 products 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 products 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 products because the biosimilar manufacturer would not have to recoup the research and development and marketing costs associated with the branded product. The development and commercialization of any competing products 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 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 payors 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 products, anywhere in the world, for the treatment of UCD or HE, which are chemically similar to RAVICTI, they may still develop and commercialize products that compete with RAVICTI. For example, products approved for indications other than UCD and HE may still compete with RAVICTI if physicians prescribe such products off-label for UCD or HE. We are also aware that Orphan Europe is conducting a clinical trial of carglumic acid to treat some of the UCD enzyme deficiencies for which RAVICTI was approved. Promethera 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 N¬acetylglutamate 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' products could limit the demand, and the price we are able to charge, for our products. We will not successfully execute on our business objectives if the market acceptance of our products is inhibited by price competition, if physicians are reluctant to switch from existing products to our products, or if physicians switch to other new products or choose to reserve our products for use in limited patient populations.

In addition, established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license and develop novel compounds that could make our products 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, acquire or in-license medicines that are superior to other products in the market;
- attract qualified clinical, regulatory, and sales and marketing personnel;
- obtain patent and/or other proprietary protection for our products and technologies;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new product candidates.

If we are unable to maintain or realize the benefits of orphan drug exclusivity for RAVICTI for the treatment of UCD in the United States, we may face increased competition.*

Under the Orphan Drug Act of 1983, the FDA may designate a product 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 was granted orphan drug exclusivity by the FDA in May 2013, which we expect will provide the drug with orphan drug marketing exclusivity in the United States until February 2020, seven years from the date of its approval. 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 assure 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, we could be subject to generic competition and revenues from RAVICTI could decrease materially. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as RAVICTI despite orphan drug exclusivity, we may face increased competition and lose market share with respect to RAVICTI. RAVICTI does not have orphan drug exclusivity in the EU or other regions of the world.

Our business operations may subject us to numerous commercial disputes, claims and/or lawsuits.*

Operating in the pharmaceutical industry, particularly the commercialization of pharmaceutical products, 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 products, 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. 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 and have assumed responsibility for the on-going Hatch Waxman litigation with Par related to RAVICTI. 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.

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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 previously entered into a rebate agreement with a PBM, pursuant to which we were required to pay certain rebates on certain of our products that were reimbursed by health plans contracting with the PBM with respect to their formularies. In 2014, we sent a notice alerting the PBM of certain material breaches by the PBM under the agreement and indicating that the agreement would automatically terminate if the material breaches were not cured within 30 days. Among other things, the breaches by the PBM involved repeated invoices that included claims for rebates which were not eligible for payment under the agreement. Following the 30-day period, during which the PBM did not take action to cure the breaches or formally respond to the notice, we sent another notice informing the PBM that the agreement was terminated as of the end of the 30-day period in accordance with its terms and we ceased paying further rebates under the agreement. On November 6, 2014 and March 9, 2015, we received letters from the PBM asserting that the breaches we alleged in our termination notice were not material breaches and therefore the agreement was not terminated and remains in effect. In addition, the PBM has claimed that we owe approximately $68 million in past price protection and utilization rebates related to VIMOVO and DUEXIS and further rebates on sales of VIMOVO and DUEXIS continuing after the date we believe the agreement was terminated. The substantial majority of these rebate claims relate to price protection rebates on VIMOVO which we believe are precluded under the agreement, particularly because VIMOVO was not covered under the agreement until after we had established an initial price for VIMOVO under one of our national drug codes. Based upon the terms of the agreement and the PBM's actions, we believe that the PBM's claims in its November 6, 2014 and March 9, 2015 letters are without merit and we intend to vigorously defend against them. However, we cannot predict the outcome of this dispute, including whether it will result in litigation. If we are unsuccessful in defending against the PBM's claims, and in light of the significant number of health plans that contract with the PBM, we could be forced to make substantial payments to the PBM for past and/or future rebates, at least through 2014. While the stated term of the agreement was through 2015, even if the PBM successfully argued that we did not validly terminate the contract due to material breach, we do not expect that we would owe further rebates in 2015 based on certain actions of the PBM. We also believe that we may have claims for damages that we could assert against the PBM. In any event, resolving the dispute with the PBM or being subject to related litigation 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 an 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. On September 30, 2015, which was the end of the option exercise period, CBI informed us that it chose not to exercise its option to acquire all of the outstanding stock of Andromeda. In connection with the agreement, the parties appointed a steering committee to oversee the completion of an on-going clinical trial of DiaPep277 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 closing, CBI transferred to Hyperion beneficial ownership of 96,612 shares of Hyperion common stock. CBI cannot complete the transfer until it obtains a valid tax certificate from the tax authority in Israel exempting CBI from an obligation to withhold Israeli taxes in connection with the transfer. It is possible that this transfer will be delayed and it is possible we may owe taxes in Israel in connection with this transfer.

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 recently completed Phase 3 clinical trial of DiaPep277, the potential termination of DiaPep277 development by us and the return of related intellectual property to Yeda as CBI chose not to 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. For example, in February 2015, one of the former employees of Andromeda sued Hyperion in Israeli labor court for wrongful dismissal and related employment causes of action. 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.

Our pursuit of a potential acquisition of Depomed, including our involvement in related litigation, could be expensive and time consuming and divert attention and resources from the operation of our business.*

On July 7, 2015, we announced a proposal to acquire all of the outstanding shares of common stock of Depomed, Inc., or Depomed, for $29.25 per share in an all-stock transaction valued at approximately $3.0 billion. Subsequently, on July 21, 2015, we increased the value of our all-stock proposal to $33.00 per share, contingent on Depomed entering into good faith discussions regarding a transaction. On August 13, 2015, the Company reiterated its proposal to acquire Depomed and fixed the exchange ratio of such offer based at 0.95 ordinary shares of the Company for each share of Depomed common stock based on the 15-day volume weighted average price of an ordinary share of the Company as of August 12, 2015.

On September 8, 2015, the Company commenced an exchange offer for all outstanding shares of Depomed common stock. Under the terms of the offer, tendering Depomed shareholders would be able to exchange each share of Depomed common stock for 0.95 ordinary shares of the Company. The exchange offer is subject to certain conditions set forth including the redemption or removal of certain poison pill rights that the Depomed board has the unilateral ability to remove, the tender of a majority of the total number of outstanding Depomed shares on a fully diluted basis, expiration or termination of the waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act") and other applicable antitrust laws and regulations, and the affirmative vote at a special meeting of the shareholders of the Company to approve the issuance of the Company's ordinary shares in the acquisition. Based on publicly available information, Horizon believes that only clearance under the HSR Act is required and the waiting period under the HSR Act expired effective October 9, 2015. If the exchange offer is completed, the Company would expect to complete a second-step merger as soon as practicable thereafter in order to acquire the remaining Depomed shares. At this time, no merger agreement or other agreement relating to the acquisition proposal has been entered into between Depomed and us, and we cannot provide any assurance as to whether or when a transaction with Depomed will be consummated or the terms thereof.

In addition to the exchange offer, on September 8, 2015, the Company filed a definitive solicitation statement seeking the support of Depomed shareholders to call two related special meetings to consider and vote on proposals to remove and replace the current Depomed board of directors and to amend the Depomed bylaws to facilitate shareholder action.

On October 15, 2015, the Company filed a definitive proxy statement in connection with an extraordinary general meeting of the Company's shareholders scheduled for November 13, 2015. The principal purpose of this meeting is to approve the issuance of the Company's ordinary shares in connection with the proposed acquisition of Depomed.

On October 26, 2015, the Company extended the expiration of its exchange offer to acquire all of the outstanding shares of common stock of Depomed to November 20, 2015.

On August 3, 2015, HPI filed a lawsuit in the Superior Court of the State of California, County of Santa Clara, naming as defendants Depomed and the members of its board of directors, or the Depomed Board, Vicente J. Anido, Jr., Karen A. Dawes, Louis J. Lavigne, Jr., Samuel R. Saks, James A. Schoeneck, Peter D. Staple and David B. Zenoff. The lawsuit is captioned Horizon Pharma, Inc. v. Vicente J. Anido, Jr., et al., Case Number 1:15-cv-283835. The lawsuit alleges that the adoption by the Depomed Board of the Rights Agreement dated as of July 12, 2015 between Depomed and Continental Stock Transfer & Trust Company, as Rights Agent, or the Depomed Rights Agreement, and Sections 2(b), 2(c), 2(d), and 5(d) of Depomed's Amended and Restated Bylaws, effective July 12, 2015, or the Depomed Bylaws, violates the General Corporation Law of the California Corporations Code, constitutes ultra vires acts and breaches the fiduciary duties of the members of the Depomed Board. The lawsuit seeks, among other things, an order (i) declaring that the Depomed Rights Agreement and Sections 2(b), 2(c), and 2(d) of the Depomed Bylaws are invalid under California law, (ii) declaring that the members of the Depomed Board breached their fiduciary duties by enacting the Depomed Rights Agreement and Sections 2(b), 2(c), 2(d), and 5(d) of the Depomed Bylaws, (iii) enjoining the members of the Depomed Board from relying on, implementing, applying or enforcing either the

Depomed Rights Agreement or Sections 2(b), 2(c), 2(d), or 5(d) of the Depomed Bylaws, (iv) enjoining the members of the Depomed Board from taking any improper action designed to impede, or which has the effect of impeding, our proposed combination with Depomed or our efforts to acquire control of Depomed and (v) compelling the members of the Depomed Board to redeem the Depomed Rights Agreement or to render it inapplicable to us. The Superior Court has calendared for November 5, 2015 a hearing on a preliminary injunction motion by HPI to enjoin enforcement of the Depomed Rights Agreement and Sections 2(b), 2(c) and 2(d) of the Depomed bylaws.

Also on August 3, 2015, Depomed filed a lawsuit in the Superior Court of the State of California, County of Santa Clara, against us. The lawsuit is captioned Depomed, Inc. v. Horizon Pharma plc, Case Number 1:15-cv-283834. The complaint asserts a claim for violation of the California Uniform Trade Secrets Act and breach of contract in connection with our alleged use in pursuing the proposed combination with Depomed of information obtained pursuant to a confidentiality agreement entered into as part of our consideration of a business arrangement with Janssen Pharmaceuticals Inc. relating to its U.S. rights to NUCYNTA®, which are now owned by Depomed. The complaint also alleges that we made fraudulent and materially misleading statements to Depomed's shareholders. The lawsuit seeks, among other relief, an injunction (i) to prevent us from continuing our allegedly improper and unlawful use of Depomed's confidential and trade secret data and (ii) to prevent us from continuing to make and failing to correct our allegedly false and misleading statements in connection with the proposed combination of Depomed. The Superior Court has calendared for November 5, 2015 a hearing on a preliminary injunction motion by Depomed.

Our continued pursuit of an acquisition of Depomed, including the related litigation described above and any new litigation, may be expensive and time consuming to us, may ultimately be unsuccessful, and could divert attention and resources from the operation of our business and from our pursuit of other business opportunities that we may also view as beneficial.

A variety of risks associated with operating our business and marketing our products 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, Switzerland, Germany and in Israel (through Andromeda). Moreover, LODOTRA is currently being marketed in a limited number of countries outside the United States, and Mundipharma is in the process of obtaining pricing and reimbursement approval for, and preparing to market, LODOTRA in other European countries, as well as in certain Asian, Latin American, Middle Eastern and African countries. Also, 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 and positive opinion of the EMA for marketing approval of RAVICTI in the EU is pending before the European Commission for a binding decision. 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 products;
- 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;
- compliance with Swiss laws with respect to our Horizon Pharma Switzerland GmbH subsidiary, including laws requiring maintenance of cash in the subsidiary to avoid over-indebtedness, which requires Horizon Pharma Switzerland GmbH to maintain assets in excess of its liabilities;
- 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, 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;
- compliance with Israeli laws with respect to Andromeda;
- 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 U.K.'s Bribery Act 2010, or the U.K. Bribery Act. The FCPA and similar anti-corruption laws generally prohibit the 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 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, acquire or in-license other product candidates or products, our business and prospects would be limited.*

A key element of our strategy is to develop, acquire or in-license and commercialize a portfolio of other products or product candidates in addition to our current products, through business or product 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 or in-license approved or clinically enabled product candidates for therapeutic indications that complement or augment our current products, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting, acquiring or in-licensing promising products or product 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 product or product 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 or in-license suitable products or product 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 or in-license businesses or new products, our business and prospects will be limited.

Moreover, any product candidate we acquire or in-license 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 product candidates are prone to the risk of failure that is inherent in pharmaceutical product development, including the possibility that the product 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 products 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 products, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates to follow our existing products or be able to acquire other products to expand our existing portfolio, and our business and prospects would be harmed.

Our November 2013 acquisition of the U.S. rights to VIMOVO, the September 2014 acquisition of Vidara, our October 2014 acquisition of the U.S. rights to PENNSAID 2%, the May 2015 acquisition of Hyperion 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 acquired the U.S. rights to VIMOVO in November 2013, merged our business with Vidara's business in September 2014, acquired the U.S. rights to PENNSAID 2% in October 2014 and acquired Hyperion in May 2015. From time to time, we may seek to engage in additional strategic transactions with third parties, such as acquisitions of companies or divisions of companies, asset purchases or in-licensing of products or product 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 with respect to its continued involvement in such litigation, and we 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. Moreover, 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 our acquisition of the U.S. rights to VIMOVO, the acquisition of Vidara, our acquisition of the U.S. rights to PENNSAID 2%, the acquisition of Hyperion or any other strategic transaction, we will achieve the anticipated revenues, net income or tax 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 and Bermuda. Prior to the acquisition of Vidara, 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, 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 products 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, and as a result of the fact that the former stockholders of Horizon Pharma, Inc., or HPI, owned (within the meaning of Section 7874) less than 80% (by both vote and value) of the combined entity's stock immediately after the acquisition of Vidara, we believe our parent company qualifies as a foreign corporation for U.S. federal income tax purposes following the acquisition of Vidara. 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 acquisition Vidara would be nullified and we may not be able to recoup the significant investment in completing the transaction.

Moreover, even if such requirements were met in the Vidara acquisition, the IRS may assert that the transactions contemplated in connection with the Depomed acquisition (including the formation and capitalization of Diosail Merger Corporation, our wholly-owned Delaware subsidiary, the exchange offer, the second-step merger and, possibly, a third-step merger that may be executed immediately following the second-step merger, if deemed appropriate by us, in which Depomed would be merged with and into Diosail Merger Two Corporation, our directly, wholly-owned Delaware subsidiary that has been formed solely to participate in a possible third-step merger), or the Transactions, should be integrated with the Vidara acquisition. In the event the IRS were to prevail with such assertion, we would be treated as a U.S. corporation for U.S. federal tax purposes. Because we did not consider the possibility of acquiring Depomed before February of 2015, we do not believe that the Transactions should be integrated with the Vidara acquisition. As a consequence, we do not believe that we should be treated as a U.S. corporation for U.S. federal income tax purposes as a result of the Transactions, but we cannot assure you that the IRS will agree with this position and/or would not successfully challenge our status as a foreign corporation. If such a challenge by the IRS were successful, significant adverse tax consequences would result for us.

We may be subject to Irish stamp duty in connection with the proposed Depomed acquisition.*

Irish stamp duty generally arises in connection with the transfer of shares of an Irish company or the transfer of shares in a non-Irish company in exchange for shares of an Irish company, in each case unless an exemption applies. Accordingly, the proposed exchange of shares of Depomed common stock for the issue of our parent company ordinary shares would be subject to Irish stamp duty unless exemption applies. We believe, however, that the Company may be able to obtain a confirmation from the Revenue Commissioners of Ireland that:

(a) Irish stamp duty should not apply to a transfer of shares of Depomed common stock through the systems of the Depository Trust Company ("DTC"), where those shares of Depomed common stock are listed on NASDAQ; and
(b) the Revenue Commissioners of Ireland will not seek to levy Irish stamp duty in connection with the transfer of shares of Depomed common stock where such duty arises solely because the issue of the Company's ordinary shares comprises a portion of the consideration being paid in respect of such transfer because each of those transactions, taken separately (i.e., the issue of the Company's ordinary shares and the transfer of shares of Depomed common stock), would not individually give rise to such a charge.

The Company intends to request the aforementioned written confirmation of the Revenue Commissioners of Ireland and an acknowledgement that no Irish stamp duty will apply in connection with the second-step merger by operation of law.

There is no guarantee however that the Revenue Commissioners will provide either or both of the above referenced confirmations in connection with the offer or the second-step merger. In the event that the Revenue Commissioners do not grant an applicable confirmation and Irish stamp duty applies to a transfer of a share of Depomed common stock in connection with the offer or second-step merger, such stamp duty would be chargeable at a rate of 1 percent of the

market value of such share of Depomed common stock as at the date of transfer and Purchaser would be liable for paying such tax.

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. 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.

Notice 2014-52, issued in September 2014, states that the Treasury and the IRS expect to issue guidance to further limit the benefits of inversions including guidance that will address earnings stripping by foreign multinational corporations through interest deductions on inter-company debt. Limitations on the ability of our U.S. group to deduct interest on inter-company debt could result in more of our 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, or OECD, 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 to implement these standards, including country by country reporting. 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 at 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 comprised of our Chairman, President and Chief Executive Officer, Timothy P. Walbert; our Executive Vice President and Chief Business Officer, Robert F. Carey; our Executive Vice President and Chief Financial Officer, Paul W. Hoelscher; our Executive Vice President, Company Secretary and Managing Director, Ireland, David Kelly; our Executive Vice President and Chief Commercial Officer, John J. Kody; our Executive Vice President, Corporate Development, Barry J. Moze; our Executive Vice President, Research and Development and Chief Medical Officer, Jeffrey W. Sherman, M.D.; our Executive Vice President, General Counsel, Brian Beeler; our Executive Vice President, Strategy and Investor Relations, John B. Thomas; and our Executive Vice President, Global Orphan Business Unit and International Operations, George Hampton. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide performance stock units and stock options and restricted stock units that vest over time. The value to employees of performance stock units, 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 affairs, 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 products and product candidates will be limited.

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We are, with respect to our current products, and will be, with respect to any other product or product candidate for which we obtain FDA approval or which we acquire or in-license, subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense. Additionally, any other product candidate, if approved by the FDA, 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 products.*

Any regulatory approvals that we obtain for our product candidates may also be subject to limitations on the approved indicated uses for which the product 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 product candidate. In addition, with respect to our currently FDA-approved products (and with respect to our product candidates, if approved), the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product 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 current good manufacturing practices, or cGMPs, good clinical practices, or GCPs, international conference on harmonization regulations, or ICH regulations, and good laboratory practices, which are regulations and guidelines enforced by the FDA for all of our products 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 RA for which the FDA recently granted an extension with a final report due date of 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.

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 products 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 products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. 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.

Later discovery of previously unknown problems with a product, 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 product, withdrawal of the product from the market, or voluntary or mandatory product 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 product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; 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 products, which could make it difficult for us to sell our products profitably or to successfully execute planned product price increases.*

Market acceptance and sales of our products 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 products will depend in part on the availability of governmental and third-party payor reimbursement for the cost of our products. 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 payors often provide reimbursement for products 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 products and product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased 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 product pricing, reimbursement and usage, which may adversely affect our product 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 product price increases, or limit the amount by which we may be able to increase our product prices, which may adversely affect our product sales and results of operations.

Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Moreover, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Additionally, one third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product, 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 products. 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. Also, as noted above, we are currently in an ongoing contract and rebate dispute with a U.S. PBM involving VIMOVO and DUEXIS, the outcome of which we cannot at this time determine, and which has the potential to negatively impact our relationship with that PBM, which could affect their coverage and/or reimbursement treatment of our other products. Additional healthcare plan formularies may also exclude our products from coverage due to the actions of these PBMs, future price increases we may implement, our use of the PME 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 products and increase the likelihood that prescriptions for our products are not filled.

Outside of the United States, the success of our products, including LODOTRA and, if widely approved, DUEXIS, as well as BUPHENYL and, if approved outside the United States, RAVICTI, 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, LODOTRA is approved in over 35 countries outside the United States, and 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. 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 products 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 product or as volumes increase. Recently, many countries in the EU have increased the amount of discounts required on pharmaceutical products, 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. For example, legislation was recently enacted in Germany that will increase the rebate on prescription pharmaceuticals and likely lower the revenues from the sale of LODOTRA in Germany that we would otherwise receive. As a result of these pricing practices, it may become difficult to achieve 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 payors, we cannot be sure that coverage and reimbursement will be available for any of our products in any additional markets or for any other product candidates that we may develop. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize our products.

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. There may be additional pressure by payors and healthcare providers to use generic drugs that contain the active ingredients found in BUPHENYL, DUEXIS, PENNSAID 2%, RAYOS/LODOTRA and VIMOVO or any other product candidates that we may develop, acquire or in-license. If we fail to successfully secure and maintain coverage and adequate reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products 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 payors concerning certain promotional approaches that we may implement such as our PME program or any other co-pay or free product programs whereby we assist qualified patients with certain out-of-pocket expenditures for our product. If we are unsuccessful with our PME program or any other co-pay initiatives or free product programs, 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 access in areas such as managed care contract rebates, PME 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 products 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, 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 product. An expansion in the government’s role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using our products, reduce product 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 drug product 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 new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% 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. Moreover, certain politicians, including presidential candidates, have announced plans to regulate the prices of pharmaceutical products. The majority of our products are purchased by private payors, 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 payors. 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 products 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, as described in greater detail in the Government Regulation section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which is incorporated by reference herein. 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, payors, 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 product 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 PME program, any other co-pay initiatives or free product 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 business activities or arrangements of Hyperion prior to our acquisition of Hyperion 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 products or any other product candidate that we develop may cause undesirable side effects or have other properties that could delay or prevent regulatory approval or commercialization, result in product re-labeling or withdrawal from the market or have a significant impact on customer demand.*

Undesirable side effects caused by any product 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.

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

In addition, if we or others identify undesirable side effects caused by our products or any other product candidate that we may develop that receives marketing approval, or if there is a perception that the product 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 product or place restrictions on the way it is prescribed;

- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product 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 products, our ability to generate significant revenues from the sale of these products 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 product candidates and our business could be substantially harmed.*

We have agreements with third-party contract research organizations, 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 of RAVICTI. We may also have the need to enter into other such agreements in the future if we were to develop other product candidates or conduct clinical trials in additional indications for our existing products. 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 to conduct the FA Phase 3 study 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. 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 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 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, or EC, approvals in order to conduct our clinical trials. Delays by IRBs and ECs in providing such approvals may delay our clinical trials.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs 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 products and product candidates. As a result, our results of operations and the commercial prospects for our products and product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO 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, 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.

In addition, 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 Idiopathic Arthritis for which the FDA recently granted an extension with a final report due date of December 2015. We have also assumed Hyperion's post-marketing obligations and commitments to conduct studies in UCD patients during the first two months of life and from two months to two years of age. 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.

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 our 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 product candidates may not be predictive of the results of later-stage clinical trials. Product 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.

With respect to our on-going Phase 3 clinical trial to evaluate ACTIMMUNE for the treatment of FA, and to the extent that we are required to conduct additional clinical development of any of our existing or later acquired products or we conduct clinical development of earlier stage product candidates or for other additional indications for ACTIMMUNE or RAYOS/LODOTRA, we may experience delays in these clinical trials. 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 institutional review board 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 product 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 product 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 product 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 product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If our experiences delays in the completion of, or if we terminate, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product 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 product 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 product candidates.

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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 Deerfield, Illinois. If our Dublin or Deerfield 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 products and third-party logistics partners to ship our products. Our ability to obtain commercial supplies of our products 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.

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

We face an inherent risk of product liability as a result of the commercial sales of our products and the clinical testing of our product candidates. For example, we may be sued if any of our products or product 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 product, 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 products and product 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 products or product 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;
- product 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 products or product 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 products we develop. We currently carry product liability insurance covering our clinical studies and commercial product sales in the amount of $30 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 products in the United States, and/or the potential commercial launches of DUEXIS, LODOTRA or RAVICTI in additional markets, 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 product 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

We have incurred significant operating losses since our inception, and have not yet achieved profitability.*

We have a limited operating history and even less history operating as a combined organization following the acquisitions of Vidara and Hyperion. We have financed our operations primarily through equity and debt financings and have incurred significant operating losses since our inception. We had net income of $15.5 million for the nine months ended September 30, 2015 and net losses of $263.6 million, $149.0 million and $87.8 million for the years ended December 31, 2014, 2013 and 2012, respectively. As of September 30, 2015, we had an accumulated deficit of $705.2 million. Our losses have resulted principally from costs incurred in our development activities for our products and product candidates, commercialization activities related to our products, cash 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 become profitable in the future, whether and when we achieve this will depend on the revenues we generate from the sale of our products being sufficient to cover our operating expenses, and we have not achieved profitability to date.

We have limited sources of revenues and significant expenses. Even if we achieve profitability in the future, 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 become profitable depends upon our ability to generate revenues from sales of our products. We have a limited history of commercializing our products as a company, and commercialization has been primarily in the United States. We may never be able to successfully commercialize our products or develop or commercialize other products in the United States, 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 products and any other product candidates for which we obtain approval;
- obtaining FDA approvals for additional indications for ACTIMMUNE;

- securing additional foreign regulatory approvals for LODOTRA, DUEXIS and RAVICTI; and
- developing, acquiring or in-licensing and commercializing a portfolio of other product candidates in addition to our current products.

Even if we do generate additional product sales, we may not be able to sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our ordinary shares and could impair our ability to raise capital, expand our business, diversify our product 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 products in the United States, including due to the substantial expansion of our sales force we completed in connection with our November 2013 acquisition of the U.S. rights to VIMOVO and the additional expansion of our sales force in connection with our acquisitions of Hyperion and the U.S. rights to PENNSAID 2%;
- complete the regulatory approval process, and any future required clinical development related thereto, for our products and product candidates;
- potentially acquire other businesses or additional complementary products or products that augment our current product portfolio, including costs associated with refinancing debt of acquired companies; and
- conduct clinical trials with respect to ACTIMMUNE for FA and any other potential indications beyond CGD or SMO, as well as conduct post-marketing requirements and commitments with respect to our products and products we acquire, including RAVICTI.

While we believe that our existing cash and cash equivalents will be sufficient to fund our operations to the point of generating continuous positive cash flow 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, acquire or in-license additional products 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 products or product 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 or in-licensing. We also could be required to:

- seek collaborators for one or more of our current or future product 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 product 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.

Our Swiss subsidiary, Horizon Pharma Switzerland GmbH, is subject to Swiss laws regarding over-indebtedness that require Horizon Pharma Switzerland GmbH to maintain assets in excess of its liabilities. As of September 30, 2015, Horizon Pharma Switzerland GmbH was not over-indebted. However, Horizon Pharma Switzerland GmbH has previously been over-indebted, including at December 31, 2013. We will continue to monitor and review Horizon Pharma Switzerland GmbH’s financial position and, as necessary, will address any over-indebtedness, which could require us to have cash at Horizon Pharma Switzerland GmbH in excess of its near-term operating needs and could affect our ability to have sufficient cash at our other subsidiaries to meet their near-term operating needs.

Any of the above events could significantly harm our business, financial condition and prospects and cause the price of our ordinary shares to decline.

We have incurred substantial direct and indirect costs as a result of the acquisition of Hyperion.*

We have incurred substantial expenses in connection with and as a result of completing the acquisition of Hyperion and, over a period of time following the completion of the acquisition of Hyperion, we expect to incur substantial additional expenses in connection with coordinating the businesses, operations, policies and procedures of the combined company. Many of the expenses that will be incurred, by their nature, are difficult to estimate accurately.

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.*

As of September 30, 2015, we had $1,141.0 million book value, or $1,274.0 million principal amount, of indebtedness, including $400.0 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, or the credit agreement, providing for (i) a five-year $400.0 million term loan facility, or 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, or the 2015 Senior Secured Credit Facility. In September 2015, we repaid $1.0 million in principal amount from this facility. 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 the acquisition of Hyperion;
- 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 2015 Senior Secured Credit Facility, 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 2015 Senior Secured Credit Facility, 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;
- limiting our ability to obtain additional financing for working capital, capital expenditures, debt service requirements, acquisitions, and general corporate or other purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business or market conditions and placing us at a competitive disadvantage compared to our competitors who are less 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.

The indenture governing the 2023 Senior Notes and the credit agreement impose, and the terms of any future indebtedness may 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, merge, 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

products 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 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.

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 our outstanding 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 lenders under the credit agreement could foreclose against the assets securing the borrowings then outstanding; and
- we could be forced into bankruptcy or liquidation.

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 U.S. commercialization activities for our products, to potentially fund additional regulatory approvals of DUEXIS, ACTIMMUNE, RAYOS/LODOTRA and RAVICTI, to potentially fund development, life cycle management or manufacturing activities of ACTIMMUNE, RAYOS/LODOTRA and PENNSAID 2% for other indications, to potentially fund additional product or business acquisitions 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 utilize net operating loss carry forwards and certain other tax attributes may be limited.*

Under Section 382 of the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation’s ability to use pre-change net operating loss carry forwards and other pre-change tax attributes to offset post-change income may be limited. In September 2014, the acquisition of Vidara triggered an “ownership change” limitation and, as a result, we will be subject to annual limits on our ability to utilize the net operating loss carry forwards of Horizon Pharma Inc. and its subsidiaries. We estimate this will result in annual limits of $89.5 million in 2015, 2016 and 2017. 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 $26.0 million, $19.6 million and $14.6 million in 2015, 2016 and 2017 respectively. During the second quarter, we also recognized additional net operating losses and federal tax credits as a result of the Hyperion acquisition on May 7, 2015 in the amount of $32.4 million of net operating losses and $26.5 million of federal tax credits. We continue to carryforward the annual limitation related to Hyperion of $50.0 million resulting from the last ownership change date in 2014. However, we expect that the annual limitation will be increased as a result of the Hyperion acquisition and the fair value of Hyperion. The net operating loss carry forward limitation is cumulative such that any use of the carry forwards 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 acquisition of Vidara. As a result, it is not currently expected that HPI 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 acquisition of Vidara. Notwithstanding this limitation, we expect that HPI will be able to fully utilize its 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 HPI does not generate taxable income consistent with our expectations.

Any limitation on our ability to use our net operating loss carry forwards, including the carry forwards of Hyperion, 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. In addition, 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.

At September 30, 2015, we had $684.3 million of cash and cash equivalents consisting of cash, money market funds and short-term bank time deposits. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since September 30, 2015, 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 marketable securities 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.*

U.S. 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 U.S. generally accepted accounting principles 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 indenture governing our outstanding notes and the credit agreement 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 credit agreement and the indenture governing the 2023 Senior Notes 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;
- merge, 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.

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 indenture governing the 2023 Senior Notes, which could permit the administrative agent or the trustee, as applicable, to, or permit the lenders or the holders of the 2023 Senior Notes to cause the administrative agent or the trustee, as applicable, to, declare all or part of any outstanding loans or the 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 either the credit agreement or the indenture governing the 2023 Senior Notes could also lead to an event of default under the terms of the other agreement and the indentures governing our outstanding 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 the acquisitions of the U.S. rights to VIMOVO and PENNSAID 2%, the acquisition of Vidara and the acquisition of Hyperion become impaired, we could have to take significant charges against earnings.*

In connection with the accounting for acquisitions of the U.S. rights to VIMOVO and PENNSAID 2%, the acquisition of Vidara and the acquisition of Hyperion, 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 products and product 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 products and product 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 or in-license may fail to result in issued patents with claims that cover our products in the United States or in other foreign countries. If this were to occur, early generic competition could be expected against our current products and other product candidates in development. There is no assurance that the potentially relevant prior art relating to our patents and patent applications has been found, which 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 products for many years, it is possible that these products 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.

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc., or Par, advising that Par had filed an ANDA with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par's ANDA and/or prevent Par from selling a generic version of DUEXIS. In January 2013, we filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par's ANDA and/or prevent Par from selling a generic version of DUEXIS.

On August 21, 2013, we entered into the Par settlement agreement and Par license agreement with Par relating to the patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both us and Par of all claims that were or could have been asserted in the litigation and that arise out of the specific patent issues that were the subject of the litigation, including all resulting damages or other remedies.

Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par's generic version of DUEXIS in the United States after the generic entry date 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. The License covers all patents owned or controlled by us during the term of the Par license agreement that would, absent the License, be infringed by the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States. Unless terminated sooner pursuant to the terms of the Par license agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in 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.

Under the Par license agreement, we also agreed, on behalf of ourselves and our affiliates, not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by us during the term of the Par license agreement based on the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States.

The Par license agreement may be terminated by us if Par commits a material breach of the agreement that is not cured or curable within 30 days after we provide notice of the breach. We may also terminate the Par license agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the Par license agreement will terminate automatically upon termination of the Par settlement agreement.

On July 15, 2013, we received a Paragraph IV Patent Certification from Actavis advising that Actavis had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Actavis, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc. seeking an injunction to prevent the approval of the ANDA.

On October 1, 2015, we, as well as Jagotec, entered into a License and Settlement Agreement, or the Actavis Settlement Agreement, with Actavis relating to the our and Jagotec's on-going patent infringement litigation. In accordance with legal requirements, we, Jagotec and Actavis have agreed to submit the Actavis Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The parties have agreed to file stipulations of dismissal with the court regarding the litigation. 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' generic version of RAYOS tablets.

Under the Actavis Settlement Agreement, we and Jagotec granted Actavis a non-exclusive license to manufacture and commercialize Actavis' 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' 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 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 may be able to enter the market earlier in 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.

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

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 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 November 13, 2014, we received a Paragraph IV Patent Certification from Actavis FL advising that Actavis FL had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Actavis FL has not advised us as to the timing or status of the FDA's review of its filing. On December 23, 2014, we filed suit in the United States District Court for the District of New Jersey against Actavis seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges 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 generic versions of PENNSAID 2% prior to the expiration of the patents. The subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Actavis action.

On June 30, 2015, we 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, we 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. And on September 17, 2015, we 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 December 2, 2014, we 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 advising that Paddock had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On January 9, 2015, we 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, we 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 the patents.

On May 6, 2015, we entered into the Perrigo settlement agreement with Perrigo relating to our on-going patent infringement litigation. The Perrigo settlement agreement provides for a full settlement and release by both us 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%.

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 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 in 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.

Under the Perrigo settlement agreement, we also agreed not to sue or assert any claim against Perrigo for infringement of any patent or patent application owned or controlled by us during the term of 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%, we may be required to supply Perrigo PENNSAID 2% 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.

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 before the expiration of 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; (ii) Lupin; (iii) Mylan; and (iv) Actavis. Patent litigation in the United States District Court for the District of New Jersey against a fifth generic company, Anchen, was dismissed on June 9, 2014 after Anchen recertified under Paragraph III. We understand 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 Pozen VIMOVO patents, which are still the subject of patent litigations. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

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 and May 13, 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. On June 18, 2015, we amended the complaints to add a charge of infringement of U.S. Patent No. 8,865,190.

The cases asserting U.S. Patent Nos. 8,557,285 and 6,926,907 have been consolidated for discovery. The court has issued a claims construction order for these cases and has set a pretrial schedule, but has not yet set a trial date.

The cases asserting U.S. Patent Nos. 8,852,636, 8,858,996, and 8,865,190 have not been consolidated for discovery. The court has not issued a claims construction order or set a pretrial schedule.

We understand the cases arise from Paragraph IV 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. We understand 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 and February 9, 2015; the Actavis notice letters were dated March 29, 2013, November 5, 2013 and October 9, 2015; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order and has set a pretrial schedule but has not yet set a trial date.

On February 24, 2015, Dr. Reddy's Laboratories, Inc. filed a Petition for 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, Dr. Reddy's Laboratories, Inc.'s petition for inter partes review of U.S. Patent No. 8,557,285 was denied by the United States Patent and Trademark Office.

On May 21, 2015, the Coalition for Affordable Drugs VII LLC 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. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On June 5, 2015, the Coalition for Affordable Drugs VII LLC filed another Petition for IPR of U.S. Patent No. 8,858,996, one of the patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 7, 2015, the Coalition for Affordable Drugs VII LLC 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. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 12, 2015, the Coalition for Affordable Drugs VII LLC filed another Petition for IPR of U.S. Patent No. 8,945,621, one of the patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not the IPR will be instituted.

On August 19, 2015, Lupin filed Petitions for IPR of U.S. Patent Nos. 8,858,996, 8,852,636, and 8,865,190, all patents in litigation in the above referenced VIMOVO cases. The Patent Trial and Appeal Board has not yet issued decisions with regard to whether or not IPRs will be instituted.

On or about December 19, 2014, we filed a Notice of Opposition to a European patent, EP 2611457, to Roberto Testi, et al., covering compositions and methods for treating FA with interferon gamma, e.g., ACTIMMUNE. In the EU, the grant of a patent may be opposed by one or more private parties.

On February 2, 2015, we 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 advising that Taro had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On March 13, 2015, we 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, the Horizon Subsidiaries entered into a settlement and license agreement, or the Taro Settlement Agreement, with Taro relating to our on-going patent infringement litigation. In accordance with legal requirements, the Horizon Subsidiaries and Taro have agreed to submit the Taro Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The Horizon Subsidiaries and Taro have also agreed to file stipulations of dismissal with the courts regarding the litigation. 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 in 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 our 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 us during the term of 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 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 March 18, 2015, we 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%. Lupin Limited has not advised us as to the timing or status of the FDA's review of its filing. On April 30, 2015, we 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 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 the patents. The subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Lupin action.

On June 30, 2015, we 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, we 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, we 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%.

We received from IGI 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 IGI had filed an ANDA with the FDA for a generic version of PENNSAID 2%. IGI has not advised us as to the timing or status of the FDA's review of its filing. On May 21, 2015, we filed suit in the United States District Court for the District of New Jersey against IGI seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that IGI 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 the patents. The subject patents are listed in the FDA's Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of IGI's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The court has not yet set a trial date for the IGI action.

On June 30, 2015, we filed suit in the United States District Court for the District of New Jersey against IGI for patent infringement of U.S. Patent No. 9,066,913. On August 11, 2015, we filed suit in the United States District Court for the District of New Jersey against IGI 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 IGI 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%.

We received from 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%. Amneal has not advised us as to the timing or status of the FDA's review of its filing. On May 15, 2015, we 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 alleges 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 the patents. The subject patents are listed in the FDA's 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. The court has not yet set a trial date for the Amneal action.

On June 30, 2015, we 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, we 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, we 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 March 17, 2014, Hyperion received notice from Par that it had filed an ANDA with the FDA seeking approval for a generic version of our product 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, and U.S. Patent No. 8,642,012, titled "Methods of treatment using ammonia scavenging drugs," which expires in September 2030, are invalid and/or will not be infringed by Par's manufacture, use or sale of the product for which the ANDA was submitted. Par did not challenge the validity, enforceability, or infringement of the primary composition of matter patent for RAVICTI, U.S. Patent No. 5,968,979 titled "Triglycerides and ethyl esters of phenylalkanoic acid and phenylalkenoic acid useful in treatment of various disorders," which would have expired on February 7, 2015, but as to which Hyperion has been granted an interim term of extension until February 7, 2016. Hyperion filed suit in the United States District Court for the Eastern District of Texas, Marshall Division, against Par on April 23, 2014 seeking an injunction to prevent the approval of Par's ANDA and/or to prevent Par from selling a generic version of RAVICTI, and we have taken over and are responsible for this patent litigation. On September 15, 2015, we received notice from Par that it had filed a Paragraph IV Patent Certification alleging that U.S. Patent No. 9,095,559 is invalid and/or will not be infringed by Par's manufacture, use or sale of the product for which the ANDA was submitted.

On April 29, 2015, Par filed petitions for IPR of the '215 patent and the '012 patent. The Patent Trial and Appeal Board has not yet issued a decision with regard to whether or not IPRs will be instituted.

We received from Lupin Limited a Paragraph IV Patent Certification dated September 4, 2015 against Orange Book listed U.S. Patent Nos. 8,404,215 and 8,642,012 advising that Lupin had filed an ANDA with the FDA for a generic version of RAVICTI. Lupin has not advised the Company as to the timing or status of the FDA's review of its filing. On October 19, 2015, we 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 U.S. Patent Nos. 8,404,215, 8,642,012, and 9,095,559 by filing an ANDA seeking approval from the FDA to market generic versions of RAVICTI prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. The 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. The court has not yet set a trial date for the Lupin action.

We intend to vigorously defend our intellectual property rights relating to DUEXIS, VIMOVO, ACTIMMUNE, PENNSAID 2%, RAYOS and RAVICTI, but we cannot predict the outcome of the Dr. Reddy's cases, the Lupin cases, the Mylan cases, or the Actavis cases related to VIMOVO, the Watson matter, and the Lupin matter related to PENNSAID 2%, or the Par Pharmaceutical matter related to RAVICTI. Any adverse outcome in these matters or any new generic challenges that may arise could result in one or more generic versions of DUEXIS, VIMOVO, ACTIMMUNE, PENNSAID 2%, RAYOS or RAVICTI 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 DUEXIS, VIMOVO, ACTIMMUNE, PENNSAID 2%, RAYOS and/or RAVICTI, 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 DUEXIS, VIMOVO, ACTIMMUNE, RAYOS/LODOTRA, PENNSAID 2% or RAVICTI 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 products. 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 products or any other product 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 it had been granted an interim extension of this patent's term through February 7, 2016 while the United States Patent and Trademark Office, or U.S. PTO, makes a final determination as to the length of the extension. We cannot be certain that the full four year term of extension for which Hyperion applied will be granted, or that there will be any extension beyond the one year interim extension. 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 product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product 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 products and/or any other product 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 product 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 product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product 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 product 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 product 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 products, 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 product 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 product 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 products, 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 SkyePharma's 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 SkyePharma 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

products 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 Pozen under which AstraZeneca has in-licensed exclusive rights under certain of Pozen's patents with respect to VIMOVO, and (iii) acquired AstraZeneca's co-ownership rights with Pozen 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 Pozen as we take over AstraZeneca's agreements with Pozen, our rights to commercialize VIMOVO in the United States may be adversely affected or terminated by AstraZeneca or Pozen.

We also license rights to patents, know-how and trademarks for ACTIMMUNE from 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 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 product 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 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

We do not know whether an active, liquid and orderly trading market for our ordinary shares will be sustained or what the market price of our ordinary shares will be and as a result it may be difficult to sell our ordinary shares.*

Although our ordinary shares are listed on The NASDAQ Global Select Market, an active trading market for our shares may never be sustained. Further, an inactive market may impair our ability to raise capital by selling our ordinary shares and may impair our ability to enter into strategic partnerships or acquire companies or products by using our ordinary shares as consideration.

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

The trading price of our ordinary shares has been highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. 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 products, particularly our commercialization of our products in the United States;
- actions or announcements by third-party or government payors with respect to coverage and reimbursement of our products;
- 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 products and product candidates;
- unanticipated serious safety concerns related to the use of our products;

- adverse regulatory decisions;
- changes in laws or regulations applicable to our business, products or product 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 product 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, acquire, and/or in-license additional product candidates or obtain approvals for additional indications for our existing product candidates;
- introduction of new products or services offered by us or our competitors;
- our inability to effectively manage our growth;
- overall performance of the equity markets 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 stocks 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. 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 Vidara's and Hyperion's business 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 products 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 Vidara, Vidara 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 the former Vidara 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. In addition, while Hyperion has been subject to some of the requirements of Section 404, our independent registered public accounting firm has never been required to provide an attestation report on the effectiveness of Hyperion's internal control over financial reporting, and we may otherwise encounter difficulties in integrating Hyperion's internal controls within our current internal control framework. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, as well as retain and work with consultants with such knowledge. Moreover, 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 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. In the fourth quarter of 2014 and the first and second quarters of 2015, we entered into separate, privately-negotiated conversion agreements with certain holders of our 5.00% Convertible Senior Notes due 2018, or the Convertible Senior Notes. Under the 2015 conversion agreements, the holders agreed to convert an aggregate principal amount of $89.0 million of Convertible Senior Notes held by them and we agreed to settle such conversions by issuing 16,594,793 ordinary shares. In addition, pursuant to the conversion agreements, we made an aggregate cash payment of $16.7 million to the holders for additional exchange consideration and $1.7 million of accrued and unpaid interest, and recognized a non-cash charge of $11.7 million related to the extinguishment of debt as a result of the note conversions. As of September 30, 2015, there were no Convertible Senior Notes remaining outstanding. We may enter into similar agreements with respect to the Exchangeable Senior Notes from time to time.

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 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% 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 shares or publish inaccurate or unfavorable research about our business, our share price would likely 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.

We may become involved in securities class action litigation that 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. We may become involved in this type of litigation in the future. Even if we are successful in defending against any such claims, litigation could result in substantial costs and may be a distraction to our management, and may result in unfavorable results 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, 2015:

- In July 2015, we issued an aggregate of 11,571 ordinary shares to OTA LLC upon the cash exercise of warrants and we received proceeds of $52,879 representing the aggregate exercise price of such warrants.
- In July 2015, we issued an aggregate of 625,000 ordinary shares to Heights Capital Management upon the cash exercise of warrants and we received proceeds of $2,856,250 representing the aggregate exercise price of such warrants.

- In July 2015, we issued an aggregate of 113,500 ordinary shares to OTA LLC upon the cash exercise of warrants and we received proceeds of $518,695 representing the aggregate exercise price of such warrants.
- In July 2015, we issued an aggregate of 15,306 ordinary shares to Capital Ventures International upon the cashless exercise of a warrant to purchase an aggregate of 17,259 ordinary shares.
- In August 2015, we issued an aggregate of 100 ordinary shares to Iron Horse Capital upon the cash exercise of warrants and we received proceeds of $457 representing the aggregate exercise price of such warrants.

The offers, sales and issuances of the securities described above were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance on Rule 506 of Regulation D in that each issuance of securities was to an accredited investor under Rule 501 of Regulation D and did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

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 6, 2015 By: /s/ Timothy P. Walbert
Timothy P. Walbert
Chairman, President and Chief Executive Officer

(Principal Executive Officer)

Date: November 6, 2015 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(8)	Agreement and Plan of Merger, dated March 29, 2015, by and among Horizon Pharma, Inc., Ghrian Acquisition Inc. and Hyperion Therapeutics, Inc.*
3.1(3)	Memorandum and Articles of Association of Horizon Pharma Public Limited Company.
4.1(4)	Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Comerica Bank.
4.2(4)	Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Hercules Technology Growth Capital, Inc.
4.3(4)	Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Comerica Bank.
4.4(4)	Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Hercules Technology Growth Capital, Inc.
4.5(5)	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.
4.6(6)	Form of Warrant issued by Horizon Pharma, Inc. in Public Offering of Units.
4.10(7)	Indenture, dated as of March 13, 2015, by and between Horizon Pharma Investment Limited, Horizon Pharma Public Limited Company and U.S. Bank National Association.
4.11(7)	Form of 2.50% Exchangeable Senior Note due 2022 (included in Exhibit 4.10).
4.12(9)	Indenture, dated as of April 29, 2015, by and between Horizon Pharma Financing Inc. and U.S. Bank National Association.
4.13(9)	Form of 6.625% Senior Note due 2023 (included in Exhibit 4.12).
4.14(10)	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.
10.1+	

	Horizon Pharma Public Limited Company Director Share Clog Program Trust Deed and Form of Clog Letter.
10.2+	Executive Employment Agreement, dated as of August 6, 2015, by and between Horizon Pharma Inc., Horizon Pharma USA, Inc. and George P. Hampton.
10.3**	Confidential Settlement and License Agreement, dated September 9, 2015, by and among Horizon Pharma Ireland Limited, HZNP Limited, Horizon Pharma USA, Inc., Taro Pharmaceuticals USA, Inc. and Taro Pharmaceuticals Industries, Ltd.
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

* 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.

** 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 management contract or compensatory plan.

(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 Current Report on Form 8-K, filed on September 19, 2014.

(4) Incorporated by reference to Horizon Pharma, Inc.'s Registration Statement on Form S-1 (No. 333-168504), as amended.

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

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

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

(8) 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.

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

(10) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on May 11, 2015.