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FORM 10-Q

Shire plc - N/A

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Quarterly report with a continuing view of a company's financial position

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Quarterly Period ended March 31, 2016

Commission File Number: 0-29630

SHIRE PLC

(Exact name of registrant as specified in its charter)

Jersey (Channel Islands)
(State or other jurisdiction of incorporation or organization)

98-0601486
(I.R.S. Employer Identification No.)

**5 Riverwalk, Citywest Business Campus, Dublin 24, Republic of
Ireland**
(Address of principal executive offices and zip code)

+353 1 429 7700
(Registrant's telephone number, including area code)

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, and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (232,405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of April 22, 2016 the number of outstanding ordinary shares of the Registrant was 592,140,306.

THE “SAFE HARBOR” STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

Statements included herein that are not historical facts, including without limitation statements concerning future strategy, plans, objectives, expectations and intentions, the anticipated timing of clinical trials and approvals for, and the commercial potential of, inline or pipeline products are forward-looking statements. Such forward-looking statements involve a number of risks and uncertainties and are subject to change at any time. In the event such risks or uncertainties materialize, Shire's results could be materially adversely affected. The risks and uncertainties include, but are not limited to, the following:

- the proposed combination with Baxalta Incorporated (“Baxalta”) may not be completed due to a failure to satisfy certain closing conditions, including any shareholder or regulatory approvals or the receipt of applicable tax opinions;
- disruption from the proposed transaction with Baxalta may make it more difficult to conduct business as usual or maintain relationships with patients, physicians, employees or suppliers;
- the combined company may not achieve some or all of the anticipated benefits of Baxalta's spin-off from Baxter International, Inc. (“Baxter”) and the proposed transaction may have an adverse impact on Baxalta's existing arrangements with Baxter, including those related to transition, manufacturing and supply services and tax matters;
- the failure to achieve the strategic objectives with respect to the proposed combination with Baxalta may adversely affect the company's financial condition and results of operations;
- products and product candidates may not achieve commercial success;
- product sales from ADDERALL XR and INTUNIV are subject to generic competition;
- the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payers in a timely manner for the company's products may affect future revenues, financial condition and results of operations, particularly if there is pressure on pricing of products to treat rare diseases;
- supply chain or manufacturing disruptions may result in declines in revenue for affected products and commercial traction from competitors; regulatory actions associated with product approvals or changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, an increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- the successful development of products in various stages of research and development is highly uncertain and requires significant expenditures and time, and there is no guarantee that these products will receive regulatory approval;
- the actions of certain customers could affect the company's ability to sell or market products profitably, and fluctuations in buying or distribution patterns by such customers can adversely affect the company's revenues, financial condition or results of operations;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to the company's activities in the highly regulated markets in which it operates may result in significant legal costs and the payment of substantial compensation or fines;
- adverse outcomes in legal matters, tax audits and other disputes, including the company's ability to enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on the company's revenues, financial condition or results of operations;
- Shire is undergoing a corporate reorganization and was the subject of an unsuccessful acquisition proposal and the consequent uncertainty could adversely affect the company's ability to attract and/or retain the highly skilled personnel needed to meet its strategic objectives;
- failure to achieve the strategic objectives with respect to Shire's acquisition of NPS Pharmaceuticals Inc. (“NPS”) or Dyax Corp. (“Dyax”) may adversely affect the company's financial condition and results of operations;
- the company is dependent on information technology and its systems and infrastructure face certain risks, including from service disruptions, the loss of sensitive or confidential information, cyber-attacks and other security breaches or data leakages that could have a material adverse effect on the company's revenues, financial condition or results of operations;
- the company may be unable to retain and hire key personnel and/or maintain its relationships with customers, suppliers and other business partners;
- difficulties in integrating Dyax or Baxalta into Shire may lead to the company not being able to realize the expected operating efficiencies, cost savings, revenue enhancements, synergies or other benefits at the time anticipated or at all; and

other risks and uncertainties detailed from time to time in Shire's, Dyax's or Baxalta's filings with the Securities and Exchange Commission (“SEC”), including those risks outlined in “ITEM 1A: Risk Factors” in Shire's and Baxalta's Annual Reports on Form 10-K for the year ended December 31, 2015.

All forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Except to the extent otherwise required by applicable law, we do not undertake any obligation to republish revised forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

The following are trademarks either owned or licensed by Shire plc or its subsidiaries, which are the subject of trademark registrations in certain territories, or which are owned by third parties as indicated and referred to in this Form 10-Q:

ADDERALL XR® (mixed salts of a single entity amphetamine)
BUCCOLAM® (midazolam hydrochloride oromucosal solution)
CINRYZE® (C1 esterase inhibitor [human])
DAYTRANA® (trademark of Noven Pharmaceutical Inc. ("Noven"))
DERMAGRAFT® (trademark of Organogenesis Inc. ("Organogenesis"))
ELAPRASE® (idursulfase)
ELVANSE® (lisdexamfetamine dimesylate)
FIRAZYR® (icatibant)
FOSRENOL® (lanthanum carbonate)
GATTEX® (teduglutide [rDNA origin])
INTUNIV® (guanfacine extended release)
KALBITOR® (ecallantide)
LIALDA® (trademark of Nogra International Limited)
MEZAVANT® (trademark of Giuliani International Limited)
NATPAR® (parathyroid hormone)
NATPARA® (parathyroid hormone (rDNA))
PENTASA® (trademark of Ferring B.V. Corp ("Ferring"))
REPLAGAL® (agalsidase alfa)
RESOLOR® (prucalopride)
REVESTIVE® (teduglutide)
SENSIPAR® (cinacalcet HCl)
VANCOCIN® (trademark of ANI Pharmaceuticals Inc.)
VPRIV® (velaglucerase alfa)
VYVANSE® (lisdexamfetamine dimesylate)
XAGRID® (anagrelide hydrochloride)
ZEFFIX® (trademark of GlaxoSmithKline plc ("GSK"))
3TC® (trademark of GSK)

SHIRE PLC
Form 10-Q for the three months ended March 31, 2016
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PART I: FINANCIAL INFORMATION
ITEM 1: FINANCIAL STATEMENTS

SHIRE PLC

UNAUDITED CONSOLIDATED BALANCE SHEETS

	Notes	March 31, 2016 \$'M	December 31, 2015 \$'M
ASSETS			
Current assets:			
Cash and cash equivalents		69.0	135.5
Restricted cash		22.3	86.0
Accounts receivable, net	5	1,312.7	1,201.2
Inventories	6	680.0	635.4
Prepaid expenses and other current assets	8	314.4	197.4
Total current assets		<u>2,398.4</u>	<u>2,255.5</u>
Non-current assets:			
Investments		50.4	50.8
Property, plant and equipment ("PP&E"), net		837.6	828.1
Goodwill	9	6,881.9	4,147.8
Other intangible assets, net	10	13,715.6	9,173.3
Deferred tax asset		129.1	121.0
Other non-current assets		42.3	33.3
Total assets		<u>24,055.3</u>	<u>16,609.8</u>
LIABILITIES AND EQUITY			
Current liabilities:			
Accounts payable and accrued expenses	11	1,978.2	2,050.6
Short-term borrowings	13	2,211.3	1,511.5
Other current liabilities	12	157.1	144.0
Total current liabilities		<u>4,346.6</u>	<u>3,706.1</u>
Non-current liabilities:			
Long-term borrowings	13	4,654.0	69.9
Deferred tax liability		3,543.3	2,205.9
Other non-current liabilities	14	1,216.7	798.8
Total liabilities		<u>13,760.6</u>	<u>6,780.7</u>
Commitments and contingencies	15		

SHIRE PLC
UNAUDITED CONSOLIDATED BALANCE SHEETS (continued)

	Notes	March 31, 2016 \$'M	December 31, 2015 \$'M
Equity:			
Common stock of 5p par value; 1,000 million shares authorized; and 601.2 million shares issued and outstanding (2015: 1,000 million shares authorized; and 601.1 million shares issued and outstanding)		59.0	58.9
Additional paid-in capital		4,507.8	4,486.3
Treasury stock: 9.1 million shares (2015: 9.7 million shares)		(302.8)	(320.6)
Accumulated other comprehensive loss	16	(159.4)	(183.8)
Retained earnings		6,190.1	5,788.3
Total equity		<u>10,294.7</u>	<u>9,829.1</u>
Total liabilities and equity		<u>24,055.3</u>	<u>16,609.8</u>
The accompanying notes are an integral part of these Unaudited Consolidated Financial Statements.			

SHIRE PLC
UNAUDITED CONSOLIDATED STATEMENTS OF INCOME

		3 Months Ended March 31,	
	Notes	2016	2015
		\$'M	\$'M
Revenues:			
Product sales		1,627.3	1,423.2
Royalties		79.2	62.8
Other revenues		2.8	2.4
Total revenues		<u>1,709.3</u>	<u>1,488.4</u>
Costs and expenses:			
Cost of product sales		248.6	227.8
Research and development ("R&D")		217.1	193.7
Selling, general and administrative ("SG&A")		609.5	506.6
Gain on sale of product rights		(4.2)	(5.2)
Reorganization costs	3	3.3	15.2
Integration and acquisition costs	4	91.1	75.7
Total operating expenses		<u>1,165.4</u>	<u>1,013.8</u>
Operating income from continuing operations		543.9	474.6
Interest income		1.0	2.0
Interest expense		(44.7)	(9.6)
Other (expense)/income, net		(8.5)	4.3
Total other expense, net		<u>(52.2)</u>	<u>(3.3)</u>
Income from continuing operations before income taxes and equity in losses of equity method investees		491.7	471.3
Income taxes		(82.1)	(57.4)
Equity in losses of equity method investees, net of taxes		(0.1)	(1.0)
Income from continuing operations, net of taxes		<u>409.5</u>	<u>412.9</u>
Gain/(loss) from discontinued operations, net of taxes	7	9.5	(2.5)
Net income		<u>419.0</u>	<u>410.4</u>

SHIRE PLC
UNAUDITED CONSOLIDATED STATEMENTS OF INCOME (continued)

	Notes	3 Months Ended March 31, 2016	2015
Earnings per ordinary share - basic			
Earnings from continuing operations		\$ 0.69	\$ 0.70
Gain/(loss) from discontinued operations		\$ 0.02	-
Earnings per ordinary share - basic		\$ 0.71	\$ 0.70
Earnings per ordinary share - diluted			
Earnings from continuing operations		\$ 0.69	\$ 0.69
Gain/(loss) from discontinued operations		\$ 0.02	-
Earnings per ordinary share - diluted		\$ 0.71	\$ 0.69
Cash dividends declared per common share		-	-
Weighted average number of shares (millions):			
Basic	19	591.7	589.1
Diluted	19	593.3	592.7

The accompanying notes are an integral part of these Unaudited Consolidated Financial Statements.

SHIRE PLC
UNAUDITED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	3 Months Ended March 31,	
	2016	2015
	\$'M	\$'M
Net income	419.0	410.4
Other comprehensive income/(loss):		
Foreign currency translation adjustments	24.7	(129.5)
Unrealized (loss)/gain on available-for-sale securities (net of taxes of \$nil and \$nil)	(0.3)	0.7
Comprehensive income	443.4	281.6

The components of accumulated other comprehensive loss as of March 31, 2016 and December 31, 2015 are as follows:

	March 31,	December 31,
	2016	2015
	\$'M	\$'M
Foreign currency translation adjustments	(157.4)	(182.1)
Unrealized holding loss on available-for-sale securities, net of taxes	(2.0)	(1.7)
Accumulated other comprehensive loss	(159.4)	(183.8)

The accompanying notes are an integral part of these Unaudited Consolidated Financial Statements.

SHIRE PLC
UNAUDITED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

	Common stock number of shares M's	Common stock \$'M	Additional paid-in capital \$'M	Treasury stock \$'M	Accumulated other comprehensive loss \$'M	Retained earnings \$'M	Total equity \$'M
As of January 1, 2016	601.1	58.9	4,486.3	(320.6)	(183.8)	5,788.3	9,829.1
Net income	-	-	-	-	-	419.0	419.0
Other comprehensive income net of tax	-	-	-	-	24.4	-	24.4
Options exercised	0.1	0.1	-	-	-	-	0.1
Share-based compensation	-	-	18.3	-	-	-	18.3
Tax benefit associated with exercise of stock options	-	-	3.2	-	-	-	3.2
Shares released by employee benefit trust to satisfy exercise of stock options	-	-	-	17.8	-	(17.2)	0.6
As of March 31, 2016	601.2	59.0	4,507.8	(302.8)	(159.4)	6,190.1	10,294.7

The accompanying notes are an integral part of these Unaudited Consolidated Financial Statements.

SHIRE PLC
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

	3 Months Ended March 31,	
	2016	2015
	\$'M	\$'M
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	419.0	410.4
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	168.9	120.6
Share-based compensation	18.3	15.3
Change in fair value of contingent consideration	11.4	2.4
Unwind of inventory fair value step-up	12.8	11.2
Movement in deferred taxes	(10.1)	16.6
Gain on sale of product rights	(4.2)	(5.2)
Other, net	9.7	2.1
Changes in operating assets and liabilities		
Increase in accounts receivable	(100.9)	(85.1)
Increase/(decrease) in sales deduction accruals	73.6	(24.6)
Increase in inventory	(32.2)	(22.0)
(Increase)/decrease in prepayments and other assets	(22.2)	42.4
(Decrease)/increase in accounts and notes payable and other liabilities	(154.6)	77.5
Net cash provided by operating activities	389.5	561.6
CASH FLOWS FROM INVESTING ACTIVITIES:		
Movements in restricted cash	64.8	(14.5)
Purchases of businesses, net of cash acquired	(5,692.8)	(5,199.7)
Purchases of non-current investments and PP&E	(51.6)	(22.3)
Proceeds from short-term investments	-	54.5
Proceeds from sale of product rights	3.0	3.9
Proceeds from disposal of non-current investments	-	0.9
Other, net	2.5	-
Net cash used in investing activities	(5,674.1)	(5,177.2)

SHIRE PLC
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

	3 Months Ended March 31,	
	2016	2015
	\$'M	\$'M
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from revolving line of credit, long term and short term borrowings	6,305.0	2,230.0
Repayment of revolving line of credit, long term and short term borrowings	(995.1)	(535.2)
Debt issuance costs	(93.8)	(3.3)
Contingent consideration payments	(2.1)	(2.4)
Excess tax benefit associated with exercise of stock options	3.2	19.9
Other, net	(0.1)	0.1
Net cash provided by financing activities	5,217.1	1,709.1
Effect of foreign exchange rate changes on cash and cash equivalents	1.0	(1.6)
Net decrease in cash and cash equivalents	(66.5)	(2,908.1)
Cash and cash equivalents at beginning of period	135.5	2,982.4
Cash and cash equivalents at end of period	69.0	74.3

Supplemental information associated with continuing operations:

	3 Months Ended March 31,	
	2016	2015
	\$'M	\$'M
Interest paid	(13.9)	(5.0)
Income taxes (paid)/repaid, net	(89.6)	48.8

The accompanying notes are an integral part of these Unaudited Consolidated Financial Statements.

SHIRE PLC
NOTES TO THE UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

(a) Basis of Presentation

These interim financial statements of Shire plc and its subsidiaries (collectively "Shire" or the "Company") are unaudited. They have been prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP").

The balance sheet as of December 31, 2015 was derived from audited financial statements but does not include all disclosures required by US GAAP.

These interim unaudited consolidated financial statements should be read in conjunction with the consolidated financial statements and accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with US GAAP have been condensed or omitted from these interim financial statements. However, these interim financial statements include all adjustments, consisting of normal recurring adjustments, which are, in the opinion of management, necessary to fairly state the results of the interim period and the Company believes that the disclosures are adequate to make the information presented not misleading. Interim results are not necessarily indicative of results to be expected for the full year.

(b) Use of Estimates

The preparation of financial statements, in conformity with US GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenues and expenses, and related disclosure of contingent assets and liabilities. Estimates and assumptions are primarily made in relation to the valuation of intangible assets, sales deductions, income taxes (including provisions for uncertain tax positions and the realization of deferred tax assets), provisions for litigation and legal proceedings, contingent consideration receivable from product divestments and contingent consideration payable in respect of business combinations and asset purchases. On an on-going basis the Company evaluates its estimates, judgments and methodologies. Actual results may differ from these estimates under different assumptions or conditions.

(c) New Accounting Pronouncements

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

Adopted during the current period

Reporting requirements for development stage entities

In June 2014 the FASB simplified the existing guidance for development stage entities by removing all incremental financial reporting requirements and the exception available for development stage entities when determining whether the development stage entity is a variable interest entity. The elimination of the exception may change the consolidation analysis, consolidation decision, and disclosure requirements for a reporting entity that has an interest in an entity in the development stage. Shire adopted this guidance as of January 1, 2016. The adoption of this guidance did not impact the Company's consolidated financial position, results of operations or cash flows.

Debt Issuance Costs

In April 2015, the FASB issued a new standard that requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. In August 2015, the FASB issued additional guidance which clarified that debt issuance costs related to line-of-credit arrangements can be presented in the balance sheet as an asset and amortized over the term of the line-of-credit arrangement. The recognition and measurement guidance for debt issuance costs were not affected by these amendments.

Shire adopted this guidance as of January 1, 2016 with retroactive application. The Short-term borrowings and Long-term borrowings line items in the Consolidated Balance Sheets and related footnote disclosures for all periods presented have been adjusted. The adoption of this guidance did not impact the Company's results of operations or cash flows.

Cloud Computing Arrangement

In April 2015, the FASB issued guidance to simplify the accounting for fees paid in a cloud computing arrangement. Under the standard, if a cloud computing arrangement includes a software license, then the software license element of the arrangement should be accounted for consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the arrangement should be accounted for as a service contract. Shire adopted this guidance as of January 1, 2016 with prospective application. The adoption of this guidance did not impact the Company's consolidated financial position, results of operations or cash flows.

Measurement-Period Adjustments

In September 2015 the FASB issued guidance to simplify the accounting for adjustments related to business combinations arising within one year of the acquisition. The new standard requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined and record the effect on earnings of those changes as if the accounting had been completed at the acquisition date, and sets forth new disclosure requirements related to the adjustments. Shire adopted this guidance as of January 1, 2016 with prospective application. The adoption of this guidance did not impact the Company's consolidated financial position, results of operations or cash flows.

To be adopted in future periods

Revenue from Contracts with Customers

In May 2014 the FASB issued new accounting guidance for recognizing revenue from contracts with customers. This new standard supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The new standard also requires additional qualitative and quantitative disclosures.

In August 2015, the FASB issued additional guidance that delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date.

In March 2016, the FASB issued additional guidance on when and how much revenue to recognize when another party (an agent), along with the entity, is involved in providing a good or a service to a customer.

In April 2016, the FASB issued additional guidance on accounting for licenses of intellectual property and identifying performance obligations.

The Company is currently evaluating the method of adoption and the potential impact on its financial position and results of operations of adopting this guidance.

Leases

In February 2016, the FASB issued new accounting guidance that will require the recognition of all lease assets and lease liabilities by lessees and sets forth new disclosure requirements for those lease assets and liabilities. This standard is effective for the Company as of January 1, 2019. Early adoption is permitted. The Company is currently evaluating the potential impact on its financial position and results of operations of adopting this guidance.

Share-Based Payment Accounting

In March 2016, the FASB issued an update which involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. These amendments are effective for the Company as of January 1, 2017. Early adoption is permitted. The Company is currently evaluating the method of adoption and the potential impact on its financial position and results of operations of adopting this guidance.

2. Business Combinations

Proposed combination with Baxalta

On January 11, 2016 Shire announced the proposed combination with Baxalta. Under the terms of the merger agreement, Baxalta shareholders will receive \$18.00 in cash and 0.1482 Shire American Depositary Shares ("ADSs") per Baxalta share, or if they properly elect, 0.4446 Shire ordinary shares per Baxalta share. Based on Shire's closing ADS price on January 8, 2016, this implies a total value of \$45.57 per Baxalta share, representing an aggregate consideration of approximately \$32 billion.

Baxalta is a global biopharmaceutical company that focuses on developing, manufacturing and commercializing therapies for orphan diseases and underserved conditions in hematology, oncology and immunology.

Closing of the transaction is subject to approval by Shire and Baxalta shareholders, certain regulatory approvals, redelivery of tax opinions initially delivered at signing and other customary closing conditions and representations. The Company expects the transaction to close in early June 2016.

Acquisition of Dyax

On January 22, 2016 Shire acquired all of the outstanding common stock of Dyax for \$37.30 per share in cash. Under the terms of the merger agreement, Dyax shareholders may receive additional value through a non-tradable contingent value right worth \$4.00 per share, payable generally upon US Food and Drug Administration ("FDA") approval of SHP643 (formerly DX-2930) in Hereditary Angioedema ("HAE").

Dyax was a publicly-traded, Massachusetts-based rare disease biopharmaceutical company primarily focused on the development of plasma kallikrein ("pKal") inhibitors for the treatment of HAE. Dyax's most advanced clinical program is SHP643, a Phase 3 program with the potential for improved efficacy and convenience for HAE patients. SHP643 has received Fast Track, Breakthrough Therapy, and Orphan Drug designations by the FDA and has also received Orphan Drug status in the EU. Dyax also brings a marketed product, KALBITOR, a pKal inhibitor for the treatment of acute attacks of HAE in patients 12 years of age and older.

The acquisition of Dyax was accounted for as a business combination using the acquisition method. The preliminary acquisition-date fair value consideration is \$6,330.0 million, comprising cash paid on closing of \$5,934.0 million and the preliminary fair value of the contingent value right of \$396.0 million (maximum payable \$646.0 million). The assets acquired and the liabilities assumed from Dyax have been recorded at their preliminary fair value as of January 22, 2016, the date of acquisition. The Company's unaudited consolidated financial statements included the results of Dyax as of January 22, 2016.

The amount of Dyax's post-acquisition revenues and pre-tax losses included in the Company's unaudited consolidated statement of income for the three months ended March 31, 2016 were \$10.6 million and \$55.8 million respectively. The pre-tax loss includes charges on the unwind of inventory fair value adjustments of \$1.1 million, intangible assets amortization of \$5.8 million and integration costs of \$21.0 million.

The Company's preliminary allocation of the purchase price to the assets acquired and liabilities assumed is outlined below:

	Fair value \$'M
ASSETS	
Current assets:	
Cash and cash equivalents	241.2
Accounts receivable, net	13.3
Inventories	20.2
Other current assets	8.1
	<hr/>
Total current assets	282.8
Non-current assets:	
Property, plant and equipment, net	5.8
Goodwill	2,729.5
Other intangible assets, net	
- Currently marketed products	135.0
- In-Process Research and Development ("IPR&D")	4,100.0
- Contract based royalty arrangements	425.0
Other non-current assets	28.3
	<hr/>
Total assets	7,706.4
	<hr/>
LIABILITIES AND EQUITY	
Current liabilities:	
Accounts payable and accrued expenses	30.0
Other current liabilities	1.7
Non-current liabilities:	
Deferred tax liability	1,343.3
Other non-current liabilities	1.4
	<hr/>
Total liabilities	1,376.4
	<hr/>
Preliminary fair value of identifiable assets acquired and liabilities assumed	6,330.0
	<hr/>
Consideration	
Preliminary fair value of purchase consideration	6,330.0
	<hr/>

(a) Currently marketed product

Other intangible assets totaling \$135.0 million relate to intellectual property rights acquired for Dyax's currently marketed product, KALBITOR. The fair value of the currently marketed product has been estimated using an income approach, based on the present value of incremental after tax cash flows attributable to KALBITOR.

The estimated useful life of the KALBITOR intangible asset is 18 years, with amortization being recorded on a straight-line basis.

(b) Other intangible assets – IPR&D

The IPR&D asset of \$4,100.0 million relates to Dyax's clinical program SHP643, a Phase 3 program with the potential for improved efficacy and convenience for HAE patients. The fair value of this IPR&D asset was estimated based on an income approach, using the present value of incremental after tax cash flows expected to be generated by this development project. The estimated cash flows have been probability adjusted to take into account the stage of completion and the remaining risks and uncertainties surrounding the future development and commercialization.

The valuation of IPR&D has been based on information available at the time of the acquisition (and information obtained during the measurement period) and on expectations and assumptions that (i) have been deemed reasonable by the Company's management and (ii) are based on information, expectations and assumptions that would be available to a market participant.

The estimated probability adjusted after tax cash flows used to estimate the fair value of other intangible assets have been discounted at 9%.

(c) Other intangible assets – Royalty rights

Other intangible assets totaling \$425.0 million relate to royalty rights arising from licensing agreements of a portfolio of product candidates. This portfolio includes two approved products, marketed by Eli Lilly & Company, and various development-stage products. Multiple product candidates with other pharmaceutical companies are in various stages of clinical development for which the Company is eligible to receive future royalties and/or milestone payments.

The fair value of these royalty rights is preliminary and has been estimated using an income approach, based on the present value of incremental after-tax cash flows attributable to each royalty right.

The estimated useful lives of these royalty rights range from seven to nine years (weighted average eight years), with amortization being recorded on a straight-line basis.

(d) Goodwill

Goodwill of \$2,729.5 million, which is not deductible for tax purposes, includes the expected synergies that will result from combining the operations of Dyax with Shire, particularly those synergies expected to be realized due to Shire's structure; intangible assets that do not qualify for separate recognition at the time of the acquisition; the value of the assembled workforce; and impacted by establishing a deferred tax liability for the acquired identifiable intangible assets which have no tax basis.

In the three months ended March 31, 2016 the Company expensed \$51.7 million relating to the acquisition and integration of Dyax, which have been recorded within Integration and acquisition costs in the Company's Consolidated Statement of Income.

Supplemental disclosure of pro forma information

The following unaudited pro forma financial information presents the combined results of the operations of Shire and Dyax as if the acquisition of Dyax had occurred as of January 1, 2015. The unaudited pro forma financial information is not necessarily indicative of what the consolidated results of operations actually would have been had the acquisition been completed at the date indicated. In addition, the unaudited pro forma financial information does not purport to project the future results of operations of the combined Company.

	3 Months Ended March 31,	
	2016	2015
	\$'M	\$'M
Revenues	1,715.3	1,508.8
Net income from continuing operations	401.6	279.0
Per share amounts:		
Net income from continuing operations per share - basic	\$ 0.68	\$ 0.47
Net income from continuing operations per share - diluted	\$ 0.68	\$ 0.47

The purchase price allocation is preliminary pending final determination of the fair values of certain assets and liabilities. In particular, the fair values of inventories, intangible assets and current and deferred taxes are preliminary pending receipt of the final valuations for those items. The final determination of these fair values will be completed as soon as possible but no later than one year from the acquisition date.

The unaudited pro forma financial information above reflects the following pro forma adjustments:

- (i) an adjustment to decrease net income by \$99.2 million for the three months ended March 31, 2015 to reflect acquisition costs incurred by Shire and Dyax, and increase net income by \$99.2 million for the three months ended March 31, 2016 to eliminate acquisition costs incurred;
- (ii) an adjustment to decrease net income by \$0.7 million for the three months ended March 31, 2015 to reflect amortization of the fair value adjustments for inventory as inventory is sold;
- (iii) an adjustment to increase amortization expense by approximately \$1.3 million and \$5.4 million for the three months ended March 31, 2016 and March 31, 2015, respectively, related to the identifiable intangible assets acquired; and
- (iv) an adjustment of \$20.4 million in the three months ended March 31, 2015 to record interest expense associated with the debt incurred to partially fund the acquisition of Dyax and the amortization of related deferred debt issuance costs.

The adjustments above are stated net of their tax effects, where applicable.

Acquisition of NPS

On February 21, 2015 Shire completed its acquisition of all of the outstanding common stock of NPS. As of the acquisition date, fair value of the cash consideration paid on closing was \$5,220 million.

The acquisition of NPS added GATTEX/REVESTIVE and NATPARA/NATPAR to Shire's portfolio of currently marketed products. GATTEX/REVESTIVE is approved in the US and EU for the treatment of adults with short bowel syndrome ("SBS") who are dependent on parenteral support, a rare and potentially fatal gastrointestinal disorder. NATPARA/NATPAR is approved in the US and indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism ("HPT"), a rare endocrine disease.

The acquisition of NPS was accounted for as a business combination using the acquisition method. The assets acquired and the liabilities assumed from NPS have been recorded at their estimated fair values at the date of acquisition, February 21, 2015. The Company's consolidated financial statements include the results of NPS from February 21, 2015.

The purchase price allocation for the acquisition of NPS was finalized in the fourth quarter of 2015. The Company's allocation of the purchase price to the estimated fair value of assets acquired and liabilities assumed is outlined below:

	Fair value \$'M
ASSETS	
Current assets:	
Cash and cash equivalents	41.6
Short-term investments	67.0
Accounts receivable	33.4
Inventories	89.4
Other current assets	11.1
	<hr/>
Total current assets	242.5
Non-current assets:	
Property, plant and equipment, net	4.8
Goodwill	1,551.0
Other intangible assets	
- currently marketed products	4,640.0
- royalty rights (categorized as "Other amortized intangible assets")	353.0
	<hr/>
Total assets	6,791.3
	<hr/>
LIABILITIES	
Current liabilities:	
Accounts payable and other current liabilities	75.7
Short-term debt	27.4
Non-current liabilities:	
Long-term debt, less current portion	78.9
Deferred tax liabilities	1,385.2
Other non-current liabilities	4.5
	<hr/>
Total liabilities	1,571.7
	<hr/>
Fair value of identifiable assets acquired and liabilities assumed	5,219.6
	<hr/>
Consideration	
Cash consideration paid	5,219.6
	<hr/>

(a) Other intangible assets – Currently marketed products

Other intangible assets totaling \$4,640.0 million relate to intellectual property rights of NATPARA/NATPAR and GATTEX/REVESTIVE. The estimated fair value of the currently marketed products has been estimated using an income approach, based on the present value of incremental after tax cash flows attributable to each separately identifiable intangible asset.

The estimated useful lives of the NATPARA/NATPAR and GATTEX/REVESTIVE intangible assets are 24 years, with amortization being recorded on a straight-line basis.

(b) Other intangible assets – Royalty rights

Other intangible assets totaling \$353.0 million relate to the royalty rights arising from the collaboration agreements with Amgen Inc ("Amgen"), Janssen Pharmaceutica N.V. ("Janssen") and Kyowa Hakko Kirin Co. Ltd ("Kyowa Hakko Kirin"). Amgen markets cinacalcet HCl as Sensipar in the US and as Mimpara in the EU; Janssen markets tapentadol as Nucynta in the US; and Kyowa Hakko Kirin markets cinacalcet HCl as Regpara in Japan, Hong Kong, Malaysia, Macau, Singapore, and Taiwan. NPS is entitled to royalties from the net sales of these products.

The fair value of these royalty rights has been estimated using an income approach, based on the present value of incremental after tax cash flows attributable to each royalty right.

The estimated useful lives of these royalty rights range from four to five years (weighted average four years) with amortization being recorded on a straight-line basis.

(c) *Goodwill*

Goodwill of \$1,551.0 million, which is not deductible for tax purposes, includes the expected synergies that will result from combining the operations of NPS with the operations of Shire; particularly those synergies expected to be realized due to Shire's structure; intangible assets that do not qualify for separate recognition at the time of the acquisition; the value of the assembled workforce; and impacted by establishing a deferred tax liability for the acquired identifiable intangible assets which have no tax basis.

3. Reorganization Costs

One Shire business reorganization

On May 2, 2013, the Company initiated a reorganization to integrate three divisions into a simplified One Shire organization to drive future growth and innovation. In 2014, certain aspects of the One Shire program were temporarily suspended upon the offer by AbbVie Inc. ("AbbVie") to acquire Shire. Subsequent to the termination of AbbVie's offer in October 2014, Shire resumed its One Shire efficiency program and relocated over 500 positions to Lexington, Massachusetts from Chesterbrook, Pennsylvania and established Lexington as the Company's US operational headquarters.

In the three months ended March 31, 2016 the Company incurred reorganization costs of \$3.3 million, relating to employee termination benefits and other reorganization costs. Reorganization costs of \$346.7 million in the aggregate have been incurred since the reorganization began in May 2013. The One Shire reorganization is now substantially complete.

The liability for reorganization costs arising from the One Shire efficiency program as of March 31, 2016 is as follows:

	Opening liability as of January 1, 2016 \$'M	Amount charged to re- organization \$'M	Paid/Utilized \$'M	Closing liability as of March 31, 2016 \$'M
Involuntary termination benefits	15.0	3.3	(13.6)	4.7
Other reorganization costs	10.1	-	(10.1)	-
	25.1	3.3	(23.7)	4.7

At March 31, 2016 the reorganization cost liability was recorded within accounts payable and accrued expenses.

4. Integration and Acquisition Costs

For the three months ended March 31, 2016 Shire recorded integration and acquisition costs of \$91.1 million primarily related to the acquisition and integration of Dyax and the proposed combination with Baxalta.

For the three months ended March 31, 2015 Shire recorded integration and acquisition costs of \$75.7 million primarily related to the acquisition and integration of NPS.

5. Accounts Receivable, net

Accounts receivable at March 31, 2016 of \$1,312.7 million (December 31, 2015: \$1,201.2 million), are stated at the invoiced amount and net of reserve for discounts and doubtful accounts of \$81.9 million (December 31, 2015: \$55.8 million).

Reserve for discounts and doubtful accounts:

	2016	2015
	\$'M	\$'M
As of January 1,	55.8	48.5
Provision charged to operations	149.4	80.8
Payments/credits related to sales	(123.3)	(82.6)
As of March 31,	81.9	46.7

At March 31, 2016 accounts receivable included \$89.1 million (December 31, 2015: \$79.0 million) related to royalty income.

6. Inventories

Inventories are stated at the lower of cost or market. Inventories comprise:

	March 31, 2016	December 31, 2015
	\$'M	\$'M
Finished goods	180.1	184.9
Work-in-progress	353.6	302.0
Raw materials	146.3	148.5
	680.0	635.4

7. Results of Discontinued Operations

Following the sale of the Company's DERMAGRAFT business in January 2014, the operating results associated with the DERMAGRAFT business have been classified as discontinued operations in the consolidated statements of income for all periods presented. In the three months ended March 31, 2016 and 2015, the Company recorded a gain of \$9.5 million (net of tax of \$5.5 million) primarily related to reimbursement of legal costs and a loss of \$2.5 million (net of tax of \$1.4 million) related to costs associated with the sale, respectively.

8. Prepaid Expenses and Other Current Assets

	March 31, 2016	December 31, 2015
	\$'M	\$'M
Prepaid expenses	72.9	35.6
Deferred financing costs	70.4	11.5
Income tax receivable	66.3	73.6
Value added taxes receivable	24.2	18.2
Other current assets	80.6	58.5
	314.4	197.4

9. Goodwill

The following table provides a roll-forward of the changes in the goodwill balance:

	2016 \$'M	2015 \$'M
As of January 1,	4,147.8	2,474.9
Acquisitions	2,729.5	1,732.7
Foreign currency translation	4.6	(28.9)
As of March 31,	6,881.9	4,178.7

The increase in goodwill during the three months ended March 31, 2016 was related to our acquisition of Dyax. For a more detailed description of this transaction, please see Note 2, Business Combinations, to these Unaudited Consolidated Financial Statements.

10. Other Intangible Assets, net

	March 31, 2016 \$'M	December 31, 2015 \$'M
Amortized intangible assets		
Acquired intellectual property ("IP") rights for marketed products	9,507.2	9,371.9
Other intangible assets	800.0	375.0
	10,307.2	9,746.9
Unamortized intangible assets		
Acquired IP rights for in-process research and development ("IPR&D")	5,462.0	1,362.0
	15,769.2	11,108.9
Less: Accumulated amortization	(2,053.6)	(1,935.6)
	13,715.6	9,173.3

Other intangible assets primarily are comprised of royalty rights associated with NPS and Dyax. As of March 31, 2016 accumulated amortization includes \$1,938.6 million of accumulated amortization for intellectual property rights acquired for currently marketed products and \$115.0 million for other intangible assets. As of December 31, 2015 accumulated amortization includes \$1,852.1 million of accumulated amortization for IP rights acquired for currently marketed products and \$83.5 million for other intangible assets.

The change in the net book value of intangible assets for the three months ended March 31, 2016 and 2015 is shown in the table below:

	Intangible Assets 2016 \$'M	2015 \$'M
As of January 1,	9,173.3	4,934.4
Acquisitions	4,660.9	5,198.0
Amortization charged	(134.6)	(88.3)
Foreign currency translation	16.0	(64.1)
As of March 31,	13,715.6	9,980.0

In connection with our acquisition of Dyax on January 22, 2016, the Company acquired IP rights related to marketed products of \$135 million, IPR&D assets of \$4,100 million and royalty rights intangible of \$425 million. For a more detailed description of this transaction, please see Note 2, Business Combinations, to these Unaudited Consolidated Financial Statements.

Selling, general and administrative costs include amortization of intangible assets relating to intellectual property rights acquired of \$134.6 million for the three months ended March 31, 2016 (2015: \$88.3 million).

The Company reviews its amortized intangible assets for impairment whenever events or circumstances suggest that their carrying value may not be recoverable. Unamortized intangible assets are reviewed for impairment annually or whenever events or circumstances suggest that their carrying value may not be recoverable.

11. Accounts payable and accrued expenses

	March 31, 2016 \$'M	December 31, 2015 \$'M
Accrued rebates – Medicaid	648.4	632.2
Accrued rebates – Managed care	395.2	350.2
Trade accounts payable and accrued purchases	334.5	336.3
Sales return reserve	130.1	128.3
Accrued employee compensation and benefits payable	95.3	102.5
R&D accruals	60.0	65.3
Accrued bonuses	43.2	152.0
Other accrued expenses	271.5	283.8
	<u>1,978.2</u>	<u>2,050.6</u>

12. Other Current Liabilities

	March 31, 2016 \$'M	December 31, 2015 \$'M
Income taxes payable	66.6	73.5
Value added taxes	22.1	21.8
Contingent consideration payable	19.6	19.5
Other current liabilities	48.8	29.2
	<u>157.1</u>	<u>144.0</u>

13. Borrowings

	March 31, 2016 \$'M	December 31, 2015 \$'M
Short term borrowings:		
Borrowings under the Revolving Credit Facilities Agreement (the "RCF")	1,210.0	750.0
Borrowings under the November 2015 Facilities Agreement	987.5	-
Borrowings under the January 2015 Facilities Agreement	-	750.0
Secured non-recourse debts	13.8	11.5
	<u>2,211.3</u>	<u>1,511.5</u>
Long term borrowings:		
Borrowings under the November 2015 Facilities Agreement	4,589.7	-
Secured non-recourse debts	64.3	69.9
	<u>6,865.3</u>	<u>1,581.4</u>

For a more detailed description of the various financing agreements discussed below, please see Note 16, Borrowings, of the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

Revolving Credit Facilities Agreement

On December 12, 2014, Shire entered into a \$2,100 million revolving credit facilities agreement (the "RCF") with a number of financial institutions. As of March 31, 2016 the Company utilized \$1,210 million of the RCF. The RCF, which terminates on December 12, 2020, may be used for financing the general corporate purposes of Shire. The RCF incorporates a \$250 million US dollar and Euro swingline facility operating as a sub-limit thereof.

Term Loan Facilities Agreements

January 2016 Facilities Agreement

On January 11, 2016, Shire entered into an \$18.0 billion bridge facilities agreement (the "January 2016 Facilities Agreement") with, among others, Barclays Bank PLC and Morgan Stanley Bank International Limited, acting as mandated lead arrangers and book runners. The January 2016 Facilities Agreement comprises two credit facilities: (i) a \$13.0 billion term loan facility which, subject to a one year extension option exercisable at Shire's option, matures on January 11, 2017 ("January 2016 Facility A") and (ii) a \$5.0 billion revolving loan facility which, subject to a one year extension option exercisable at Shire's option, matures on January 11, 2017 ("January 2016 Facility B"). As of March 31, 2016, the January 2016 Facilities Agreement was undrawn.

January 2016 Facility A may be used to finance the cash consideration payable and certain costs related to the proposed combination with Baxalta. January 2016 Facility B may be used to finance the redemption of all or part of Baxalta's senior notes upon completion of the proposed combination.

November 2015 Facilities Agreement

On November 2, 2015, Shire entered into a \$5.6 billion facilities agreement (the "November 2015 Facilities Agreement"). The November 2015 Facilities Agreement comprises three credit facilities: (i) a \$1.0 billion term loan facility which, subject to a one year extension option exercisable at Shire's option, matures on November 2, 2016 ("November 2015 Facility A"), (ii) a \$2.2 billion amortizing term loan facility which matures on November 2, 2017 ("November 2015 Facility B") and (iii) a \$2.4 billion amortizing term loan facility which matures on November 2, 2018 ("November 2015 Facility C").

As of March 31, 2016, the November 2015 Facilities Agreement was utilized in full to finance the cash consideration payable and certain costs related to Shire's acquisition of Dyax.

January 2015 Facilities Agreement

On January 11, 2015, Shire entered into an \$850 million term facilities agreement with, among others, Citigroup Global Markets Limited acting as mandated lead arranger and bookrunner (the "January 2015 Facilities Agreement") with an original maturity date of January 10, 2016. The maturity date was subsequently extended to July 11, 2016 in line with the provisions within the January 2015 Facilities Agreement allowing the maturity date to be extended twice, at Shire's option, by six months on each occasion. The January 2015 Facilities Agreement was utilized to finance the purchase price paid in respect of Shire's acquisition of NPS (including certain related costs).

On September 28, 2015 the Company reduced the January 2015 Facilities Agreement by \$100 million. In January 2016 and at various points thereafter, the Company cancelled parts of the January 2015 Facilities Agreement. On February 22, 2016, the Company repaid the remaining balance of \$100 million of the January 2015 Facilities Agreement in full.

Short-term uncommitted lines of credit ("Credit lines")

Shire has access to various Credit lines from a number of banks which provide flexibility to short-term cash management procedures. These Credit lines can be withdrawn by the banks at any time. The Credit lines are not relied upon for core liquidity. As of March 31, 2016 these Credit lines were not utilized.

14. Other non-current liabilities

	March 31, 2016 \$'M	December 31, 2015 \$'M
Contingent consideration payable	862.9	456.4
Income taxes payable	201.2	195.8
Other non-current liabilities	152.6	146.6
	<u>1,216.7</u>	<u>798.8</u>

15. Commitments and Contingencies

(a) Leases

Future minimum lease payments under operating leases as of March 31, 2016 are presented below:

	Operating leases \$'M
2016	36.5
2017	39.8
2018	33.5
2019	30.7
2020	30.8
2021	29.2
Thereafter	156.5
	<u>357.0</u>

The Company leases land, facilities, motor vehicles and certain equipment under operating leases expiring through 2032. Lease and rental expense amounted to \$7.5 million and \$14.2 million for the three months ended March 31, 2016 and 2015 respectively, which is predominately included in SG&A expenses in the Company's Unaudited Consolidated Statement of Income.

(b) Letters of credit and guarantees

At March 31, 2016, the Company had irrevocable standby letters of credit and guarantees with various banks and insurance companies totaling \$60.0 million (being the contractual amounts), providing security for the Company's performance of various obligations. These obligations are primarily in respect of the recoverability of insurance claims, lease obligations and supply commitments.

(c) Collaborative and other licensing arrangements

Details of significant updates in other licensing arrangements are included below:

Licensing arrangements

The Company has entered into various collaborative and licensing arrangements where it has licensed certain product or intellectual property rights for consideration such as up-front payments, development milestones, sales milestones and/or royalty payments. In some of these arrangements Shire and the licensee are both actively involved in the development and commercialization of the licensed product and have exposure to risks and rewards dependent on its commercial success. Under the terms of these collaborative and licensing arrangements, the Company may receive development milestone payments up to an aggregate amount of \$32 million and sales milestones up to an aggregate amount of \$42 million. The receipt of these substantive milestones is uncertain and contingent on the achievement of certain development milestones or the achievement of a specified level of annual net sales by the licensee. In the three months ended March 31, 2016 the Company received cash related to up-front and milestone payments of \$0.5 million (2015: \$12.6 million). In the three months ended March 31, 2016 the Company recognized milestone income of \$1.3 million (2015: \$0.5 million) in other revenues and \$15.1 million (2015: \$9.2 million) in product sales for shipment of product to the relevant licensee.

(d) Commitments

(i) Clinical testing

At March 31, 2016 the Company had committed to pay approximately \$584 million (December 31, 2015: \$490 million) to contract vendors for administering and executing clinical trials. The timing of these payments is dependent upon actual services performed by the organizations as determined by patient enrollment levels and related activities.

(ii) Contract manufacturing

At March 31, 2016 the Company had committed to pay approximately \$334 million (December 31, 2015: \$325 million) in respect of contract manufacturing. The Company expects to pay \$159 million of these commitments in 2016.

(iii) Other purchasing commitments

At March 31, 2016 the Company had committed to pay approximately \$581 million (December 31, 2015: \$485 million) for future purchases of goods and services, predominantly relating to active pharmaceutical ingredients sourcing. The Company expects to pay \$575 million of these commitments in 2016.

(iv) Investment commitments

At March 31, 2016 the Company had outstanding commitments to purchase common stock and interests in companies and partnerships, respectively, for amounts totaling \$22 million (December 31, 2015: \$22 million) which may all be payable in 2016, depending on the timing of capital calls. The investment commitments include additional funding to certain VIEs that Shire is not the primary beneficiary.

(v) Capital commitments

At March 31, 2016 the Company had committed to spend \$43 million (December 31, 2015: \$60 million) on capital projects.

(e) Legal and other proceedings

The Company expenses legal costs when incurred.

The Company recognizes loss contingency provisions for probable losses when management is able to reasonably estimate the loss. When the estimated loss lies within a range, the Company records a loss contingency provision based on its best estimate of the probable loss. If no particular amount within that range is a better estimate than any other amount, the minimum amount is recorded. Estimates of losses may be developed before the ultimate loss is known, and are therefore refined each accounting period as additional information becomes known. In instances where the Company is unable to develop a reasonable estimate of loss, no loss contingency provision is recorded at that time. As information becomes known a loss contingency provision is recorded when a reasonable estimate can be made. The estimates are reviewed quarterly and changed when expectations are revised. An outcome

that deviates from the Company's estimate may result in an additional expense or release in a future accounting period. At March 31, 2016, reserve for litigation losses, insurance claims and other disputes totaled \$25.0 million (December 31, 2015: \$9.9 million).

The Company's principal pending legal and other proceedings are disclosed below. The outcomes of these proceedings are not always predictable and can be affected by various factors. For those legal and other proceedings for which it is considered at least reasonably possible that a loss has been incurred, the Company discloses the possible loss or range of possible loss in excess of the recorded loss contingency provision, if any, where such excess is both material and estimable.

VYVANSE

In May and June 2011, Shire was notified that six separate Abbreviated New Drug Applications ("ANDAs") were submitted under the Hatch-Waxman Act seeking permission to market generic versions of all approved strengths of VYVANSE. The notices were from Sandoz, Inc. ("Sandoz"); Amneal Pharmaceuticals LLC ("Amneal"); Watson Laboratories, Inc.; Roxane Laboratories, Inc. ("Roxane"); Mylan Pharmaceuticals, Inc. ("Mylan"); and Actavis Elizabeth LLC and Actavis Inc. (collectively, "Actavis"). Since filing suit against these ANDA filers, along with API suppliers Johnson Matthey Inc. and Johnson Matthey Pharmaceuticals Materials (collectively "Johnson Matthey"), Shire has been engaged in a consolidated patent infringement litigation in the US District Court for the District of New Jersey against the aforementioned parties (except Watson, who withdrew their ANDA).

On June 23, 2014, the US District Court for the District of New Jersey granted Shire's summary judgment motion holding that 18 claims of the patents-in-suit were both infringed and valid. On September 24, 2015, the US Court of Appeals of the Federal Circuit ("CAFC") affirmed that ruling against all of the ANDA filers and remanded the case to the trial court for further proceedings in which Shire expects the court to impose an injunction preventing all of the ANDA filers (Sandoz, Roxane, Amneal, Actavis and Mylan) from launching generic versions of VYVANSE until the expiration of these patents in 2023. The CAFC ruling overturned the infringement ruling against Johnson Matthey and the case against Johnson Matthey has been dismissed.

On March 24, 2016, Shire received a Notice of Allegation ("NOA") from Apotex Inc. ("Apotex") informing us that Apotex filed an Abbreviated New Drug Submission ("ANDS") with Health Canada seeking approval to market a generic version of VYVANSE in Canada. Shire is reviewing the contents of the NOA and if Shire applies for an order of prohibition within 45 days of the NOA, a 24-month stay of approval of the ANDS will be put into effect.

On April 14, 2016, Shire prevailed in upholding its European patent for ELVANSE. Shire initially prevailed in an opposition to its patent lodged by Johnson Matthey plc, Generics [UK] Limited (trading as Mylan) and Hexal AG and on April 14, 2016 Shire prevailed in the appeal. The decision by the appeals board of the European Patent Office is final and cannot be further appealed.

LIALDA

In May 2010, Shire was notified that Zydus Pharmaceuticals USA, Inc. ("Zydus") had submitted an ANDA under the Hatch-Waxman Act seeking permission to market a generic version of LIALDA. Within the requisite 45-day period, Shire filed a lawsuit in the US District Court for the District of Delaware against Zydus and Cadila Healthcare Limited, doing business as Zydus Cadila. A Markman hearing took place on January 29, 2015 and a Markman ruling was issued on July 28, 2015. A trial took place between March 28, 2016 and April 1, 2016 and a decision is not expected before September 2016.

In February 2012, Shire was notified that Osmotica Pharmaceutical Corporation ("Osmotica") had submitted an ANDA under the Hatch-Waxman Act seeking permission to market a generic version of LIALDA. Within the requisite 45-day period, Shire filed a lawsuit in the US District Court for the Northern District of Georgia against Osmotica. A Markman hearing took place on August 22, 2013 and a Markman ruling was issued on September 25, 2014. The court issued an Order on February 27, 2015 in which all dates in the scheduling order have been stayed.

In March 2012, Shire was notified that Watson Laboratories Inc.—Florida had submitted an ANDA under the Hatch-Waxman Act seeking permission to market a generic version of LIALDA. Within the requisite 45-day period, Shire filed a lawsuit in the US District Court for the Southern District of Florida against Watson Laboratories Inc.—Florida and Watson Pharmaceuticals, Inc., Watson Pharma, Inc. and Watson Laboratories, Inc. (collectively "Watson") were subsequently added as defendants. A trial took place in April 2013 and on May 9, 2013 the trial court issued a decision finding that the proposed generic product infringes the patent-in-suit and that the patent is not invalid. Watson appealed the trial court's ruling to the CAFC and a hearing took place on December 2, 2013. The ruling of the CAFC was issued on March 28, 2014 overruling the trial court on the interpretation of two claim terms and remanding the case for further proceedings. Shire petitioned the Supreme Court for a writ of certiorari which was granted on January 26, 2015. The Supreme Court also vacated the CAFC decision and remanded the case to the CAFC for further consideration in light of the Supreme Court's recent decision in *Teva v Sandoz*. On June 3, 2015, the CAFC reaffirmed their previous decision to reverse the District Court's claims construction and remanded the case to the US District Court for the Southern District of Florida. A trial was held on January 25-27, 2016. A ruling was issued on March 28, 2016 upholding the validity of the patent and finding that Watson's proposed ANDA product infringes the patent-in-suit. Watson appealed the ruling to the CAFC.

In April 2012, Shire was notified that Mylan had submitted an ANDA under the Hatch-Waxman Act seeking permission to market a generic version of LIALDA. Within the requisite 45-day period, Shire filed a lawsuit in the US District Court for the Middle District of Florida against Mylan. A Markman hearing took place on December 22, 2014. A Markman ruling was issued on March 23, 2015. A trial is scheduled to take place starting on September 6, 2016.

In March 2015, Shire was notified that Amneal had submitted an ANDA under the Hatch-Waxman Act seeking permission to market a generic version of LIALDA. Within the requisite 45 day period, Shire filed a lawsuit in the US District Court for the District of New Jersey against Amneal, Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Co. India Pvt. Ltd. No trial date has been set.

In September 2015, Shire was notified that Lupin Ltd. had submitted an ANDA under the Hatch-Waxman Act seeking permission to market a generic version of LIALDA. Within the requisite 45 day period, Shire filed a lawsuit in the US District Court for the District of Maryland against Lupin Ltd., Lupin Pharmaceuticals Inc., Lupin Inc. and Lupin Atlantis Holdings SA. No trial date has been set. A Markman hearing is scheduled to take place on August 22, 2016.

On October 7, 2015 the Patent Trial and Appeals Board ("PTAB") of the United States Patent Office instituted an inter partes review ("IPR") of US Patent 6,773,720 which is the patent-in-suit in the litigations referred to above. The IPR process is designed to re-assess the patentability of the claims of the patent. A decision from the PTAB is expected in October 2016.

Investigation related to DERMAGRAFT

The Department of Justice, including the US Attorney's Office for the Middle District of Florida, Tampa Division and the US Attorney's Office for Washington, DC, is conducting civil and criminal investigations into the sales and marketing practices of Advanced BioHealing Inc. ("ABH") relating to DERMAGRAFT.

Following the disposal of the DERMAGRAFT business in January 2014, Shire has retained certain legacy liabilities including any liability that may arise from this investigation. Shire is cooperating fully with these investigations. Shire is not in a position at this time to predict the scope, duration or outcome of these investigations.

Civil Investigative Demand relating to VANCOCIN

On April 6, 2012, ViroPharma Incorporated ("ViroPharma") received a notification that the United States Federal Trade Commission ("FTC") is conducting an investigation into whether ViroPharma had engaged in unfair methods of competition with respect to VANCOCIN. On August 3, 2012, and September 8, 2014, ViroPharma and Shire respectively received Civil Investigative Demands from the FTC requesting additional information related to this matter. Shire has fully cooperated with the FTC's investigation. At this time, Shire is unable to predict the outcome or duration of this investigation.

Lawsuit related to supply of ELAPRASE to certain patients in Brazil

On September 24, 2014 Shire's Brazilian affiliate, Shire Farmaceutica Brasil Ltda, was served with a lawsuit brought by the State of Sao Paulo and in which the Brazilian Public Attorney's office has intervened alleging that Shire is obligated to provide certain medical care including ELAPRASE for an indefinite period at no cost to patients who participated in ELAPRASE clinical trials in Brazil, and seeking recoupment to the Brazilian government for amounts paid for these patients to date, and moral damages associated with these claims. Shire intends to defend itself against these allegations but is not able to predict the outcome or duration of this case.

16. Accumulated Other Comprehensive Loss

The changes in accumulated other comprehensive loss, net of their related tax effects, in the three months ended March 31, 2016 and 2015 are included below:

	Foreign currency translation adjustment \$M	Unrealized holding loss on available-for- sale securities \$M	Accumulated other comprehensive loss \$M
As of January 1, 2016	(182.1)	(1.7)	(183.8)
Current period change:			
Net current period other comprehensive income/(loss)	24.7	(0.3)	24.4
As of March 31, 2016	(157.4)	(2.0)	(159.4)
	Foreign currency translation adjustment \$M	Unrealized holding (loss)/gain on available-for- sale securities \$M	Accumulated other comprehensive loss \$M
As of January 1, 2015	(25.7)	(5.8)	(31.5)
Current period change:			
Net current period other comprehensive (loss)/income	(129.5)	0.7	(128.8)
As of March 31, 2015	(155.2)	(5.1)	(160.3)

17. Financial Instruments

Treasury policies and organization

The Company's principal treasury operations are coordinated by its corporate treasury function. All treasury operations are conducted within a framework of policies and procedures approved annually by the Board of Directors. As a matter of policy, the Company does not undertake speculative transactions that would increase its credit, currency or interest rate exposure.

Interest rate risk

The Company is principally exposed to interest rate risk on any borrowings under the Company's various debt facilities. As of March 31, 2016 the Company had fully utilized the November 2015 Facilities Agreement and utilized \$1,210.0 million of the RCF. Following the closing of the proposed combination with Baxalta, the Company will also be exposed to interest rate risk on any borrowings under the January 2016 Facilities Agreement which is undrawn as of March 31, 2016. Interest on each of these facilities is set at floating rates, to the extent utilized. Shire's exposure under these facilities is to changes in US dollar interest rates.

The Company regularly evaluates the interest rate risk on its facilities. During the three months ended March 31, 2016 the Company entered into interest rate swaps with a total notional amount of \$5,100 million related to the November 2015 Facilities Agreement to manage interest rate risk associated with movements in benchmark interest rates until various dates in the fourth quarter of 2016. As of March 31, 2016 the fair value of these contracts was \$2.0 million presented within other current liabilities. The Company has not elected hedge accounting for these contracts.

For the three months ended March 31, 2016 the Company recognized \$2.0 million (2015: \$nil) of interest expense related to these contracts, which was recognized as a component of interest expense.

The Company is also exposed to interest rate risk on its restricted cash, cash and cash equivalents and on foreign exchange contracts on which interest is set at floating rates. This exposure is primarily limited to US dollar, Pounds

Sterling and Euro interest rates. As the Company maintains all of its cash, liquid investments and foreign exchange contracts on a short-term basis for liquidity purposes, this risk is not actively managed. In the three months ended March 31, 2016 the average interest rate received on cash and liquid investments was less than 1% per annum. These cash and liquid investments were primarily invested in US dollar term deposits with banks and money market and liquidity funds.

Credit risk

Financial instruments that potentially expose Shire to concentrations of credit risk consist primarily of short-term cash investments, derivative contracts and trade accounts receivable (from product sales and from third parties from which the Company receives royalties). Cash is invested in short-term money market instruments, including money market and liquidity funds and bank term deposits. The money market and liquidity funds in which Shire invests are all triple A rated by both Standard and Poor's and by Moody's credit rating agencies.

The Company is exposed to the credit risk of the counterparties with which it enters into bank term deposit arrangements and derivative instruments. The Company limits this exposure through a system of internal credit limits which vary according to ratings assigned to the counterparties by the major rating agencies. The internal credit limits are approved by the Board and exposure against these limits is monitored by the corporate treasury function. The counterparties to these derivatives contracts are major international financial institutions.

The Company's revenues from product sales in the US are mainly governed by agreements with major pharmaceutical wholesalers and relationships with other pharmaceutical distributors and retail pharmacy chains. For the year ended December 31, 2015 there were three customers in the US that accounted for 47% of the Company's product sales. However, such customers typically have significant cash resources and as such the risk from concentration of credit is considered acceptable. The Company has taken positive steps to manage any credit risk associated with these transactions and operates clearly defined credit evaluation procedures. However, an inability of one or more of these wholesalers to honor their debts to the Company could have an adverse effect on the Company's financial condition and results of operations.

A substantial portion of the Company's accounts receivable in countries outside of the United States is derived from product sales to government-owned or government-supported healthcare providers. The Company's recovery of these accounts receivable is therefore dependent upon the financial stability and creditworthiness of the relevant governments. In recent years global and national economic conditions have negatively affected the growth, creditworthiness and general economic condition of certain markets in which the Company operates. As a result, in some countries outside of the US, specifically, Argentina, Greece, Italy, Portugal and Spain (collectively the "Relevant Countries") the Company is experiencing delays in the remittance of receivables due from government-owned or government-supported healthcare providers. The Company continues to receive remittances in relation to government-owned or government-supported healthcare providers in the Relevant Countries in the three months ended March 31, 2016, including receipts of \$22.0 million and \$24.3 million in respect of Spanish and Italian receivables, respectively. The Company's exposure to Greece, both in terms of gross accounts receivable and annual revenues, is not material.

To date the Company has not incurred material losses on accounts receivable in the Relevant Countries, and continues to consider that such accounts receivable are recoverable. The Company will continue to evaluate all its accounts receivable for potential collection risks and has made provision for amounts where collection is considered to be doubtful. If the financial condition of the Relevant Countries or other Eurozone countries suffer significant deterioration, such that their ability to make payments becomes uncertain, or if one or more Eurozone member countries withdraws from the Euro, additional allowances for doubtful accounts may be required, and losses may be incurred, in future periods. Any such loss could have an adverse effect on the Company's financial condition and results of operations.

Foreign exchange risk

The Company operates in numerous countries and as a consequence has transactional and translational foreign exchange exposures.

Transactional exposure arises where transactions occur in currencies different to the functional currency of the relevant subsidiary. The main operating currencies of the Company are the US dollar, Pounds Sterling, Swiss Franc, Canadian dollar and the Euro. It is the Company's policy that these exposures are minimized to the extent practicable by denominating transactions in the subsidiary's functional currency.

Where significant exposures remain, the Company uses foreign exchange contracts (spot, forward and swap contracts) to manage the exposure for balance sheet assets and liabilities that are denominated in currencies different to the functional currency of the relevant subsidiary. These assets and liabilities relate predominantly to inter-company financing. The Company has not elected hedge accounting for these transactions. Cash flows from derivative instruments are presented within net cash provided by operating activities in the Consolidated Statements of Cash Flows, unless the derivative instruments are economically hedging specific investing or financing activities.

Translational foreign exchange exposure arises on the translation into US dollars of the financial statements of non-US dollar functional subsidiaries.

As of March 31, 2016 the Company had 49 swap and forward foreign exchange contracts and 10 interest rate swaps outstanding to manage currency risk. The swap and forward contracts mature within 90 days. The Company did not have credit risk related contingent features or collateral linked to the derivatives. The Company has master netting agreements with a number of counterparties to these foreign exchange contracts and on the occurrence of specified events, the Company has the ability to terminate contracts and settle them with a net payment by one party to the other. The Company has elected to present derivative assets and derivative liabilities on a gross basis in the Unaudited Consolidated Balance Sheet. Further details are included below:

	Fair value March 31, 2016 \$'M	Fair value December 31, 2015 \$'M
Assets Prepaid expenses and other current assets	3.0	1.9
Liabilities Other current liabilities	13.9	11.5

As of March 31, 2016 the potential effect of rights of set-off associated with the foreign exchange contracts would be an offset to both assets and liabilities of \$2.0 million (2015: \$nil), resulting in net derivative assets and derivative liabilities of \$1.0 million and \$11.9 million, respectively.

Net gains/(losses) (both realized and unrealized) arising on derivatives are recorded in the Consolidated Statements of Income as follows:

		3 Months Ended March 31, 2016 \$'M	2015 \$'M
Foreign exchange contracts and swaps	Other (expense)/income, net	(24.1)	16.3

18. Fair Value Measurement

Assets and liabilities that are measured at fair value on a recurring basis

As of March 31, 2016 and December 31, 2015 the following financial assets and liabilities are measured at fair value on a recurring basis using quoted prices in active markets for identical assets (Level 1); significant other observable inputs (Level 2); and significant unobservable inputs (Level 3).

	Fair value			
	Total \$'M	Level 1 \$'M	Level 2 \$'M	Level 3 \$'M
At March 31, 2016				
Financial assets:				
Marketable equity securities	16.9	16.9	-	-
Contingent consideration receivable	15.3	-	-	15.3
Derivative contracts	3.0	-	3.0	-
Financial liabilities:				
Derivative contracts	13.9	-	13.9	-
Contingent consideration payable	882.5	-	-	882.5
At December 31, 2015				
Financial assets:				
Marketable equity securities	17.2	17.2	-	-
Contingent consideration receivable	13.8	-	-	13.8
Derivative contracts	1.9	-	1.9	-
Financial liabilities:				
Derivative contracts	11.5	-	11.5	-
Contingent consideration payable	475.9	-	-	475.9

Marketable equity securities are included within Investments in the Unaudited Consolidated Balance Sheets. Contingent consideration receivable is included within Prepaid expenses and other current assets and Other non-current assets in the Unaudited Consolidated Balance Sheets. Contingent consideration payable is included within Other current liabilities and Other non-current liabilities in the Unaudited Consolidated Balance Sheets.

Certain estimates and judgments were required to develop the fair value amounts. The estimated fair value amounts shown above are not necessarily indicative of the amounts that the Company would realize upon disposition, nor do they indicate the Company's intent or ability to dispose of the financial instrument.

The following methods and assumptions were used to estimate the fair value of each material class of financial instrument:

- Marketable equity securities – the fair values of marketable equity securities are estimated based on quoted market prices for those investments.
- Contingent consideration receivable – the fair value of the contingent consideration receivable has been estimated using the income approach (using a probability weighted discounted cash flow method).
- Derivative contracts – the fair values of the swap and forward foreign exchange contracts have been determined using the month-end interest rate and foreign exchange rates, respectively.
- Contingent consideration payable – the fair value of the contingent consideration payable has been estimated using the income approach (using a probability weighted discounted cash flow method).

Assets and Liabilities Measured at Fair Value on a Recurring Basis Using Significant Unobservable Inputs (Level 3)

The following table provides a roll forward of the fair values of our contingent consideration receivable and payables which include Level 3 measurements:

Contingent consideration receivable

	2016	2015
	\$'M	\$'M
Balance at January 1,	13.8	15.9
Change in fair value included in earnings	4.2	5.2
Reclassification out from contingencies for payment	(3.0)	(5.9)
Currency Translation	0.3	(0.2)
Balance at March 31,	<u>15.3</u>	<u>15.0</u>

Contingent consideration payable

	2016	2015
	\$'M	\$'M
Balance at January 1,	475.9	629.9
Additions	396.4	92.1
Change in fair value included in earnings	11.4	2.4
Reclassification out from contingencies for payment	(2.0)	(2.1)
Other	0.8	1.7
Balance at March 31,	<u>882.5</u>	<u>724.0</u>

The increase in contingent consideration payable is related to the Company's acquisition of Dyax. Other primarily relates to foreign currency adjustments.

Of the \$882.5 million of contingent consideration payable as of March 31, 2016, \$19.6 million is recorded within Other current liabilities and \$862.9 million is recorded within Other non-current liabilities in the Company's balance sheet.

Quantitative Information about Assets and Liabilities Measured at Fair Value on a Recurring Basis Using Significant Unobservable Inputs (Level 3)

Quantitative information about the Company's recurring Level 3 fair value measurements is as follows:

Financial assets:		Fair Value at the Measurement Date		
At March 31, 2016	Fair value \$'M	Valuation Technique	Significant unobservable Inputs	Range
Contingent consideration receivable	15.3	Income approach (probability weighted discounted cash flow)	<ul style="list-style-type: none"> • Probability weightings applied to different sales scenarios • Future forecast consideration receivable based on contractual terms with purchaser • Assumed market participant discount rate 	<ul style="list-style-type: none"> • 10 to 90% • \$0 to \$26 million • 8.4%

Financial liabilities:		Fair Value at the Measurement Date		
At March 31, 2016	Fair value \$'M	Valuation Technique	Significant unobservable Inputs	Range
Contingent consideration payable	882.5	Income approach (probability weighted discounted cash flow)	<ul style="list-style-type: none"> • Cumulative probability of milestones being achieved • Assumed market participant discount rate • Periods in which milestones are expected to be achieved • Forecast quarterly royalties payable on net sales of relevant products 	<ul style="list-style-type: none"> • 4 to 90% • 1.2 to 12.4% • 2016 to 2030 • \$2.2 to \$6.6 million

Contingent consideration payable represents future milestones and royalties the Company may be required to pay in conjunction with various business combinations and license agreements, respectively.

The fair value of the Company's contingent consideration receivable and payable could significantly increase or decrease due to changes in certain assumptions which underpin the fair value measurements. Each set of assumptions is specific to the individual contingent consideration receivable or payable.

The carrying amounts of other financial assets and liabilities approximate their estimated fair value due to their short-term nature, such as liquidity and maturity of these amounts or because there have been no significant changes since the asset or liability was last re-measured to fair value on a non-recurring basis.

19. Earnings per Share

The following table reconciles net income and the weighted average ordinary shares outstanding for basic and diluted earnings per share for the periods presented:

	3 Months Ended March 31,	
	2016	2015
	\$'M	\$'M
Income from continuing operations, net of taxes	409.5	412.9
Gain/(loss) from discontinued operations	9.5	(2.5)
Numerator for basic and diluted earnings per share	419.0	410.4

Weighted average number of shares:

	Millions	Millions
Basic	591.7	589.1
Effect of dilutive shares:		
Share-based awards to employees	1.6	3.6
Diluted	593.3	592.7

Weighted average number of basic shares excludes shares purchased by the Employee Benefit Trust ("EBT") and under the shares buy-back program and presented by Shire as treasury stock. Share-based awards to employees are calculated using the treasury method.

The share equivalents not included in the calculation of the diluted weighted average number of shares are shown below:

	3 Months Ended March 31,	
	2016	2015
	No. of shares	No. of shares
	Millions	Millions
Share-based awards to employees	4.0	1.4

Certain stock options have been excluded from the calculation of diluted Earnings per Share ("EPS") because either their exercise prices exceeded Shire's average share price during the calculation period or the required performance conditions were not satisfied as of the balance sheet date.

20. Segment Reporting

Shire operates as one operating and reportable segment engaged in the research, development, licensing, manufacturing, marketing, distribution and sale of innovative specialist medicines to meet significant unmet patient needs.

For a more detailed description of segment disclosures about products, geographic areas and major customers, please read Note 23, Segment Reporting, of the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

In the periods set out below, revenues by major product were as follows:

	3 Months Ended March 31,	
	2016	2015
	\$'M	\$'M
VYVANSE	509.2	416.8
LIALDA/MEZAVANT	168.0	148.5
CINRYZE	164.2	148.1
FIRAZYR	128.3	92.5
ELAPRASE	123.6	125.0
REPLAGAL	103.2	97.5
ADDERALL XR	98.8	95.7
VPRIV	83.6	86.4
PENTASA	64.0	78.7
GATTEX/REVESTIVE	51.7	14.9
FOSRENOL	37.7	44.1
XAGRID	28.3	25.3
NATPARA	15.6	-
KALBITOR	10.4	-
INTUNIV	10.2	17.4
Other product sales	30.5	32.3
Total product sales	1,627.3	1,423.2

21. Taxation

For the first quarter of 2016, the effective tax rate on income from continuing operations was 17% (2015: 12%).

The effective tax rate in the first quarter of 2016 on income from continuing operations is higher than the same period in 2015 primarily due to the adverse impact in the first quarter of 2016 of the one-time re-measurement of deferred tax as a result of the Dyax acquisition and the benefit of the favorable re-measurement of uncertain tax positions in the first quarter of 2015.

22. Related Parties

ArmaGen, Inc. ("ArmaGen") is a related party as the Company owns 21% of ArmaGen common stock and the parties have a worldwide licensing and collaboration agreement to develop and commercialize AGT-182. Shire recorded R&D costs arising from the licensing and collaboration arrangement of \$0.5 million in the three months ended March 31, 2016, of which \$0.2 million was accrued and unpaid as of March 31, 2016 (2015: \$nil).

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with Shire's Unaudited Consolidated Financial Statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited Consolidated Financial Statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2015.

Significant events in the three months ended March 31, 2016 and recent developments

Products

BUCCOLAM for the treatment of prolonged, acute, and convulsive seizures in infants, toddlers, children and adolescents

- On February 18, 2016, the FDA granted orphan designation to BUCCOLAM for the treatment of status epilepticus. Further, the FDA advised that they consider status epilepticus a unique indication compared to repetitive seizures.

VYVANSE for the treatment of attention deficit hyperactivity disorder ("ADHD") and binge eating disorder ("BED") in adults

- A new drug application ("NDA") has been submitted to the FDA for VYVANSE (lisdexamfetamine dimesylate) as a chewable tablet formulation.
- A marketing application for VYVANSE BED in adults has been filed in Australia.

CINRYZE for the prophylactic treatment of HAE

- CINRYZE was launched in Canada in February 2016.

Pipeline

SHP465 for the treatment of ADHD

- On April 4, 2016, Shire announced positive topline results of SHP465 (triple-bead mixed amphetamine salts), an investigational oral stimulant medication being evaluated as a potential treatment for ADHD. In a safety and efficacy study in children and adolescents aged 6 to 17 years with ADHD, the primary efficacy analysis demonstrated that SHP465 was superior to placebo on the change from baseline in ADHD-RS-IV ("ADHD rating scale"). SHP465 was also superior to placebo in the key secondary efficacy analysis on the clinical global impression improvement scale ("CGI-I"). Adverse events were generally mild-to-moderate in severity and similar to those observed in previous SHP465 studies and with other amphetamine compounds. The completion of this study addresses an FDA requirement to evaluate the safety and efficacy of SHP465 in children and adolescents prior to filing a Class 2 resubmission for FDA approval.
- In April 2016, Shire successfully completed a required pharmacokinetics ("PK") study of SHP465. The PK properties of SHP 465 were well characterized in children and adolescents aged 6 to 17 years with ADHD and confirmed the exposure necessary for once-daily oral dosing.

FIRAZYR for the treatment of HAE in Japan

- In April 2016, Shire received preliminary results from a Phase 3 trial to evaluate the efficacy and safety of FIRAZYR for the acute treatment of angioedema attacks in Japanese patients with HAE. The data demonstrated that the efficacy and safety profile was similar between Japanese patients and those patients who participated in Shire's previously conducted Phase 3 program.

SHP625 for the treatment of cholestatic liver disease

- In April 2016, Shire received preliminary results from CAMEO, a Phase 2, open-label, non-comparative, 14 week study of SHP625 in adult patients with Primary Sclerosing Cholangitis ("PSC"). The primary objective of the study was to evaluate the safety and tolerability of SHP625 and these safety and tolerability results were consistent with previous SHP625 studies. There also were significant reductions from baseline in serum bile acids and pruritus by ItchRO score, the magnitude of the effect being consistent with what has been observed in SHP625 studies of other patient populations. However, there was no significant reduction from baseline in serum alkaline phosphatase or other liver parameters. Shire continues to analyze the totality of the SHP625 data to determine an appropriate path forward.

OTHER FIRST QUARTER 2016 DEVELOPMENTS

Proposed Combination with Baxalta

- On April 18, 2016 Shire announced that the UK Listing Authority has approved a Class 1 circular and a prospectus in relation to the proposed combination with Baxalta dated April 18, 2016. The Shire and Baxalta shareholder meetings are scheduled for May 27, 2016, with the closing to occur on or around June 3, 2016, subject to regulatory and Shire and Baxalta shareholder approvals and other customary closing conditions.
- Shire has initiated integration planning with Baxalta. Shire and Baxalta have hosted joint integration summits, and had a series of collaborative and productive interactions. The executive leadership has been selected and Shire has defined the organizational structure of the combined company.

Acquisition of Dyax

- On January 22, 2016 Shire completed its acquisition of Dyax for upfront cash consideration of \$5.9 billion. With the acquisition, Shire received the global rights to SHP643 (formerly known as DX-2930), a Phase 3, fully humanized monoclonal antibody targeting plasma kallikrein with proof-of-concept Phase 1B efficacy data. These data demonstrate a greater than 90% reduction in HAE attacks compared to placebo in the 300mg/400mg arms in patients with more than 2 attacks in the 3 months prior to study entry. SHP643 has received Fast Track, Breakthrough Therapy, and Orphan Drug designations by the FDA and has also received Orphan Drug status in the EU. If approved globally for the prevention of Type 1 and Type 2 HAE, based on current market analysis Shire estimates that SHP643 could have the potential to generate annual global sales of up to \$2 billion.

Legal Proceedings

Shire Wins Patent Trial against Watson Concerning LIALDA

- A ruling was issued by the US District Court for the Southern District of Florida on March 28, 2016 upholding the validity of the patent for LIALDA and finding that Watson Laboratories, Inc. proposed abbreviated new drug application product infringes the patent-in-suit. Watson appealed the ruling to the CAFC.

ELVANSE European Patent Upheld

- On April 14, 2016, Shire prevailed in upholding its European patent for ELVANSE. Shire initially prevailed in an opposition to its patent lodged by Johnson Matthey plc, Generics [UK] Limited (trading as Mylan) and Hexal AG and on April 14, 2016 we prevailed in the appeal. The decision by the appeals board of the European Patent Office is final and cannot be further appealed.

Products in registration as of March 31, 2016

SHP606 (lifitegrast) for the treatment of dry eye disease ("DED")

On October 16, 2015 the FDA issued a complete response letter requesting an additional clinical study to support the new drug application for lifitegrast as a treatment for the signs and symptoms of DED in adults. On October 27, 2015 Shire announced positive topline results from OPUS-3, a phase 3 efficacy and safety study of lifitegrast versus placebo. OPUS-3 compared lifitegrast to placebo administered twice daily for 84 days (12 weeks) in patients with DED, a recent history of artificial tear use within 30 days of study entry and an eye dryness score ("EDS") of 40. Lifitegrast met the single primary endpoint for patient-reported symptoms of eye dryness (mean change in EDS from baseline to week 12) (treatment difference of 7.16 (95% CI), 3.04, 11.28; p=0.0007). In addition, lifitegrast met the key secondary endpoints of symptom improvement at Days 14 and 42 (treatment difference of (95% CI) 7.85 (4.33, 11.37) and 9.32 (5.44, 13.20) respectively, (p<0.0001)). OPUS-3 also evaluated the safety and tolerability of lifitegrast based on occurrence of treatment-emergent adverse events. The safety and tolerability profile of lifitegrast in OPUS-3 was consistent with previous studies involving lifitegrast. Shire has incorporated these data into the resubmitted NDA which was filed in January of 2016. The FDA has accepted the NDA establishing a Prescription Drug User Fee Act ("PDUFA") date of July 22, 2016.

NATPAR for the treatment of HPT

NATPAR is currently under review in Europe as an adjunct to calcium and vitamin D to control hypocalcemia in patients with HPT.

INTUNIV for the treatment of ADHD in Japan

Under a collaboration agreement, Shionogi and Shire will co-develop and sell treatments for ADHD in Japan, including INTUNIV. A Phase 3 clinical program to evaluate the efficacy and safety of INTUNIV in Japanese patients aged 6 to 17 has been completed and submission of the INTUNIV application for Marketing Authorisation Application in Japan occurred on January 27, 2016.

Products in clinical development as of March 31, 2016

Phase 3 and Phase 3-ready

SHP465 for the treatment of ADHD in adults

Shire's NDA for SHP465 was previously submitted in 2006 to support the use of SHP465 as a longer-acting, once-daily treatment for ADHD in adults. With the growing adult ADHD population there is now a larger patient population and Shire expects a greater commercial need for this type of product than in 2006. SHP465 (mixed salts of a single entity amphetamine) capsules provide an extended-release of amphetamines to provide coverage of ADHD symptoms for adults.

On April 4, 2016, Shire announced positive topline results from a four-week Phase 3, randomized, double-blind, multi-center, placebo-controlled, dose-optimization, safety and efficacy study in children and adolescents aged 6-17 years with ADHD. The primary efficacy analysis of this study demonstrated that SHP465, administered as a daily morning dose, was superior to placebo on the change from baseline in ADHD-RS-IV (ADHD rating scale) total score, with a Least Squares ("LS") mean difference from placebo at Week 4 of -9.9 (95% CI: -13.0 to -6.8, $p < 0.001$), suggesting a significant improvement in ADHD symptoms. SHP465 was also superior to placebo in the key secondary efficacy analysis on the CGI-I scale, with an LS mean difference from placebo at Week 4 of -0.8 (95% CI: -1.1 to -0.5, $p < 0.001$), indicating a significantly higher proportion of patients were rated improved on the CGI-I rating scale. The CGI-I is a standardized assessment tool that allows clinicians to rate the severity of ADHD illness, change over time and efficacy of medication. Treatment-emergent adverse events $\geq 5\%$ for SHP 465-305 were decreased appetite, headache, insomnia, irritability, nausea, weight decrease and dizziness. Adverse events were generally mild to moderate in severity and similar to those observed in previous SHP465 studies and with other amphetamine compounds.

In April 2016, Shire also successfully completed a required PK study of SHP465. The PK properties of SHP 465 were well characterized in children and adolescents aged 6 to 17 years with ADHD and confirmed the exposure necessary for once daily oral dosing.

Including the Phase 3 and PK studies referenced above as well as previous studies, Shire now has a robust database of 15 clinical studies evaluating SHP465 in more than 1,100 subjects. Once the additional safety and efficacy Phase 3 trial in adults currently under way is completed later in 2016, Shire plans to add these study results to its existing SHP465 data set to submit a Class 2 resubmission for FDA approval. SHP465 remains on track for potential US launch in the second half of 2017.

FIRAZYR for the treatment of HAE in Japan

In April 2016, Shire received preliminary results from a Phase 3 trial to evaluate the efficacy and safety of FIRAZYR for the acute treatment of angioedema attacks in Japanese patients with HAE. The data demonstrated that the efficacy and safety profile was similar between Japanese patients and those patients who participated in Shire's previously conducted Phase 3 program.

SHP555 (prucalopride; marketed as RESOLOR in the EU) for the treatment of chronic constipation in the US

On January 10, 2012 Shire announced that it had acquired the rights to develop and market prucalopride in the US in an agreement with Janssen. RESOLOR was approved in 2009 in Europe for use in women for the symptomatic treatment of chronic constipation in whom laxatives fail to provide adequate relief. On June 3, 2015 Shire announced that prucalopride has been approved by the European Commission for use in adults (men and women) for the symptomatic treatment of chronic constipation in whom laxatives fail to provide adequate relief. RESOLOR is approved for use in women in Europe, so the new variation extends the use of this treatment to male patients. Shire has discussed with the FDA the requirements for filing an NDA for prucalopride and is currently working towards fulfilling those requirements in anticipation of an NDA submission.

SHP609 for the treatment of Hunter syndrome with CNS symptoms

SHP609 is in development as an enzyme replacement therapy ("ERT") delivered intrathecally for the treatment of Hunter syndrome patients with early cognitive impairment. Hunter syndrome is a Lysosomal Storage Disorder. In December 2014 the FDA granted SHP609 Fast Track designation. In addition, this product has been granted Orphan Drug designation in the US. The Company has initiated a pivotal Phase 2/3 clinical trial which is currently enrolling and an extension study is ongoing.

SHP616 (CINRYZE) for the treatment of AMR

A Phase 2 study for the treatment of AMR with SHP616 was completed in 18 patients. Shire has received FDA and European Medicines Agency ("EMA") feedback and submitted an investigational new drug application ("IND") in the second quarter of 2015. The FDA granted Fast Track designation for SHP616 in October 2015 and Shire plans to initiate enrollment in a Phase 3 study for the treatment of acute AMR in the first half of 2016.

SHP616 (CINRYZE SC) life cycle management

Shire is pursuing a subcutaneous formulation of CINRYZE for routine prophylaxis against HAE attacks in adolescent and adult patients. An IND was submitted in October 2015, and Shire initiated a Phase 3 study in the first quarter of 2016.

SHP616 (CINRYZE) for routine prophylaxis against HAE attacks in adolescent and adult patients in Japan

CINRYZE is indicated in the US for prophylaxis and in the EU for both prophylaxis and acute treatment of angioedema attacks in adolescent and adult patients with HAE. Based on feedback from the Pharmaceutical and Medical Devices Agency ("PMDA"), a Clinical Trial Notification ("CTN") was resubmitted and approved in October 2014.

SHP620 (maribavir) for the treatment of CMV infection in transplant patients

SHP620 was acquired as part of the acquisition of ViroPharma. Shire has completed two Phase 2 studies in transplant recipients. The first trial was in first-line treatment of asymptomatic CMV viremia in transplant recipients and the results of this study showed that maribavir, at all doses, was at least as effective as valganciclovir in the reduction of circulating CMV to below the limits of assay detection (undetectable plasma CMV). The second study recently completed was for the treatment of resistant/refractory CMV infection/disease in transplant recipients. The purpose of this study was to evaluate the efficacy and safety of maribavir in patients with disease which is resistant or refractory to the standard of care CMV therapy (e.g., valganciclovir, foscarnet). This study showed that maribavir, at all doses, and was effective at lowering CMV to below the limits of assay detection. Approximately two-thirds of patients across the maribavir treatment groups achieved undetectable plasma CMV DNA (viral load) within 6 weeks. This product has been granted Orphan Drug designation in both the US and EU. In late June 2015 Shire conducted an end of Phase 2 meeting with the FDA and received further clarity on the path forward. Based upon this feedback and additional FDA feedback in November, Shire plans to progress the program into Phase 3 in mid-2016.

SHP621 Oral Budesonide Suspension ("OBS"), for the treatment of adolescents and adults with Eosinophilic Esophagitis ("EoE")

With the acquisition of Meritage Pharma Inc. ("Meritage"), Shire acquired the global rights to Meritage's compound, OBS, for the treatment of adolescents and adults with EoE, a rare, chronic inflammatory GI disease. EoE is a chronic disease that is increasingly being diagnosed in children and adults, with an estimated prevalence in the US of approximately 181,000. It is characterized by inflammation and accumulation of a specific type of immune cell, called an eosinophil, in the esophagus. EoE patients may have persistent or relapsing symptoms related to esophageal dysfunction, which include dysphagia (difficulty swallowing) and food impaction.

OBS is a proprietary viscous oral formulation of budesonide that is designed to coat the esophagus where the drug can act locally. Budesonide is the active pharmaceutical ingredient in several products approved by the FDA, including products for the treatment of asthma, allergic rhinitis, ulcerative colitis and Crohn's disease. Budesonide is a corticosteroid and has an established safety profile in those diseases. The FDA has granted Orphan Drug designation to OBS for the treatment of patients with EoE. Shire initiated a Phase 3 program for the treatment of adolescents and adults with EoE in the first quarter of 2016.

SHP633 (REVESTIVE) for the treatment of short bowel syndrome ("SBS") in Japan

With the acquisition of NPS, Shire acquired the global rights to REVESTIVE an approved therapy in the US and Europe to treat adults with SBS who are dependent on parenteral support. A Phase 3 bridging study in adults was initiated in Japan in 2014 and is currently ongoing.

SHP640 for the treatment of infectious conjunctivitis

With the acquisition of Foresight on July 30, 2015, Shire acquired global rights to SHP640, a therapy in late-stage development for the treatment of infectious conjunctivitis, an ocular surface condition commonly referred to as pink eye. Foresight had completed a phase 2 proof-of-concept efficacy and safety clinical trial program for SHP640 which involved two studies in adenoviral conjunctivitis – one three-arm study and another two-arm pilot study. While the two-arm study showed a trend toward efficacy, there were too few subjects testing positive for a viral presence for the study to deliver meaningful results, and it was not statistically significant. In the three-arm study, patients treated with SHP640 showed a statistically significant improvement in rates of clinical cure and viral eradication compared to vehicle at Day 6. The Phase 2 clinical data formed the basis of a meeting with the FDA, in which Foresight discussed a Phase 3 program for viral conjunctivitis. Shire met with the FDA in the second quarter of 2016 to discuss a program in bacterial conjunctivitis, and is assessing the feedback from that meeting. The program in adenoviral conjunctivitis was previously agreed with the FDA in 2015. Shire intends to initiate a Phase 3 program in the first quarter of 2017. If approved by regulatory agencies, SHP640 has the potential to become the first agent to treat both viral and bacterial conjunctivitis.

SHP643 (formerly DX-2930) for the treatment of HAE

SHP643 is a Phase 3 novel long-acting highly potent human monoclonal antibody inhibitor of pK_{al}, which has patent protection and anticipated regulatory exclusivity beyond 2030. Proof of concept was demonstrated in a multi-center, randomized, double-blind, placebo-controlled, multiple ascending dose Phase 1B study in HAE patients, based on patients in 300mg, 400mg and placebo groups, who reported having at least two HAE attacks in the three months prior to study entry. Each patient received two treatments of SHP643 separated by 14 days. During the pre-specified, primary efficacy interval of six weeks (Day 8 to 50), the HAE attack rate was reduced by over 90% in the SHP643 combined 300mg and 400mg arms, with 0 attacks in the 300mg group (n=4; p < 0.0001) and 0.045 attacks per week in the 400 mg group (n=11; p=0.005), compared to 0.37 attacks per week in the placebo group (n=11). SHP643 was well tolerated at all dose levels with no evidence of dose-limiting toxicity up to 400 mg. The most common adverse events were HAE attacks, injection site pain, and headache, which were not appreciably higher in the SHP643 arms compared with placebo.

With a novel mechanism of action, the potential for more convenient dosing in an every other week or once monthly subcutaneous injectable form and the ability to significantly reduce HAE attacks, SHP643 has the potential to expand the market to patients currently not treated with prophylaxis therapy.

SHP643 has received Fast Track, Breakthrough Therapy, and Orphan Drug designations by the FDA and received Orphan Drug designation in the EU. Shire initiated a Phase 3 clinical trial in the first quarter of 2016.

LDX for the treatment of ADHD in Japan

LDX, currently marketed as VYVANSE in the US and ELVANSE in certain countries in the EU, for the treatment of ADHD, is under a collaboration agreement. Shionogi and Shire will co-develop and sell ADHD products in Japan, including LDX. A Phase 2/3 clinical program to evaluate the efficacy and safety of LDX in Japanese patients aged 6 to 17 was initiated in the second quarter of 2013 and is ongoing.

SHP616 (CINRYZE) new uses

In addition to initiating a Phase 3 study in AMR (discussed above), Shire is considering pursuing the development of CINRYZE in Neuromyelitis Optica ("NMO"). Shire received feedback from the FDA in the second quarter of 2015 on NMO and is in the process of determining an optimal path forward which could lead to a Phase 2/3 clinical trial in 2016.

Phase 2

SHP607 for the prevention of ROP

SHP607 is in development as a protein replacement therapy for the prevention of ROP, a rare and potentially blinding eye disorder associated with premature birth. In December 2014 Shire received notification that SHP607 was granted Fast Track designation by the FDA. In addition, this product has been granted Orphan Drug designation in both the US and EU. A Phase 2 clinical trial completed enrollment in December of 2015 and Shire anticipates topline results in mid-2016.

SHP610 for Sanfilippo A syndrome (Mucopolysaccharidosis IIIA)

SHP610 is in development as an ERT delivered intrathecally for the treatment of Sanfilippo A syndrome, a Lysosomal Storage Disorder. The Company initiated a Phase 1/2 clinical trial in the third quarter of 2010 which has now completed. Shire initiated a Phase 2b clinical trial for SHP610 which is now fully enrolled, which is designed to establish clinical proof of concept. An extension study is ongoing. The product has been granted Orphan Drug designation in the US and in the EU.

SHP625 for the treatment of cholestatic liver disease

SHP625 was acquired as part of the acquisition of Lumena Pharmaceuticals, Inc. ("Lumena") Shire is currently conducting Phase 2 studies in the following indications: Alagille Syndrome ("ALGS"), Progressive Familial Intrahepatic Cholestasis ("PFIC"), and PSC. This product has been granted Orphan Drug designation both in the US and EU.

On April 9, 2015 Shire announced that the 13-week Phase 2 IMAGO trial of SHP625 did not meet the primary or secondary endpoints in the study of 20 pediatric patients with ALGS. Mean serum bile acid levels and pruritus at the end of the study were lower in both SHP625 and placebo treated groups as compared to baseline. However, a larger Phase 2 ITCH study in pediatric patients with ALGS is currently ongoing.

In late May 2015, Shire also received results from the CLARITY study, a 13-week, double-blind, placebo-controlled Phase 2 study in combination with ursodeoxycholic acid ("UDCA") in Primary Biliary Cirrhosis ("PBC"). SHP625 did not meet the primary endpoint as measured by change in pruritus or the secondary endpoint in level of liver disease as measured by the Alkaline Phosphatase ("ALP"). However, there was a significant reduction in mean serum bile acid levels versus placebo.

In June 2015, Shire received preliminary results from an interim analysis of the INDIGO study, a 72-week open-label Phase 2 study in pediatric patients with PFIC. The interim analysis was based on the first 12 subjects who completed 13 weeks of treatment per protocol. SHP625 was well tolerated but there was no statistically significant reduction in mean serum bile levels from baseline. A change from baseline analysis was planned as there is no placebo treatment arm in this study. The changes from baseline for pruritus did reach statistical significance. Five of the 20 patients who received the drug experienced sustained decreases from baseline in serum bile acids ranging from 86 to 99% and also experienced marked reductions in pruritus as evidenced by absence of or only mild scratching at their last evaluation in this ongoing study. In this subset of patients where biomarkers of liver damage were elevated at baseline, as assessed by ALT and Total Bilirubin, these values were normalized during the study. In December 2015, updated PFIC interim data in 29 patients became available. While no new responders were identified, the five responders previously identified continued to experience sustained decreases in serum bile acids as well as marked reductions in pruritus benefits and normalization of liver parameters, in those patients who had elevated liver enzymes at baseline. Shire continues to analyze the totality of the data to determine an appropriate path forward.

In April 2016, Shire received preliminary results from CAMEO, a Phase 2, open-label, non-comparative, 14-week study of SHP625 in adult patients with PSC. The primary objective of the study was to evaluate the safety and tolerability of SHP625 and these safety and tolerability results were consistent with previous SHP625 studies. There also were significant reductions from baseline in serum bile acids and pruritus by ItchRO score, the magnitude of the effect being consistent with what has been observed in SHP625 studies of other patient populations. However, there was no significant reduction from baseline in serum alkaline phosphatase or other liver parameters. Shire continues to analyze the totality of the SHP625 data to determine an appropriate path forward.

Phase 1

SHP611 for the treatment of Metachromatic Leukodystrophy ("MLD")

SHP611 is in development as recombinant human arylsulfatase A ("rASA") delivered intrathecally every other week for the treatment of the late infantile form of MLD. This product has been granted Orphan Drug designation in the US and the EU. The Company initiated a 24 patient Phase 1/2 clinical trial in the third quarter of 2012. The primary endpoint of this trial is to determine the safety of ascending doses of rASA over 40 weeks. The secondary endpoint focuses on decline in motor function as defined by change in baseline Gross Motor Function Measure ("GMFM-88"). Exploratory endpoints include change from baseline in cerebrospinal fluid sulfatide levels and change from baseline in the total MLD severity score based on brain Magnetic Resonance Imaging ("MRI"). The trial is currently ongoing, but top line interim results were available in late April 2015.

Based upon interim data for the first 18 patients, SHP611 appeared to be well tolerated at all doses. In addition, while not statistically significant and despite a decline in GMFM-88 score across all doses, the highest dose caused a slower decline over the 40-week study period compared to the lower dose treatment groups. The higher dose group also showed encouraging data in reduced MLD MRI score and reductions of CSF sulfatide. Shire is currently enrolling an additional cohort at the highest dose and anticipates the data readout from this cohort to be available in early 2017, which will inform the future clinical and regulatory strategy for the program.

SHP622 for the treatment of FA

SHP622 is in development for the treatment of Friedreich's Ataxia and was acquired as part of the acquisition of ViroPharma. This product is a naturally occurring small molecular weight compound (indole-3-propionic acid) that prevents oxidative stress OX1 by a combination of hydroxyl radical scavenging activity and metal chelation. Phase 1 studies in healthy adults were completed in 2010. The drug was found to be generally well tolerated, and the pharmacokinetics revealed that the drug was rapidly absorbed and distributed in the body after oral administration. A Phase 1b trial to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of SHP622 in adults with FA has been completed. SHP622 was generally safe and well tolerated when administered as single and multiple PO doses. There were no severe treatment emergent adverse events ("TEAEs") or deaths reported in either the single or multiple dose groups, and the majority of TEAEs were of mild severity. However, one subject in the multiple dose group was discontinued due to a possibly related treatment emergent of angina pectoris. Overall, there were no clinically meaningful differences between SHP622 and placebo or between the single and multiple dose groups. The mean terminal elimination half-life ranged between 7.36 and 10.33 hours across all dose groups. Intersubject variability appeared to be low to moderate. Shire will continue to analyze these results and determine an optimal path forward for this program.

SHP623 for prophylactic treatment of HAE

SHP623 is a recombinant C1 inhibitor for the prophylactic treatment of HAE or other complement mediated diseases. SHP623 is intended to have a clinical profile similar to CINRYZE while providing manufacturing advantages and higher potency. Shire initiated a first-in-human study in the first quarter of 2016.

SHP626 for the treatment of nonalcoholic steatohepatitis ("NASH")

SHP626 was acquired as part of the acquisition of Lumena and is in development for the treatment of NASH, a common and often "silent" liver disease characterized by fat deposits in the liver and inflammation which can progress to significant fibrosis. A US IND was approved by the FDA in the fourth quarter of 2014, and a Phase 1b multiple dose trial has been completed.

SHP627 for the treatment of focal segmental glomerulosclerosis ("FSGS")

SHP627 was acquired as part of the acquisition of Fibrotech Therapeutics Pty Ltd. and has completed a Phase 1 study in healthy subjects and subjects with diabetic nephropathy. Additional IND enabling studies are being conducted. Phase 1 studies to determine optimal formulation and dose are expected to be initiated in 2016 followed by a Phase 2 study in FSGS patients in 2017.

SHP631 for the treatment of both the CNS and somatic manifestations in patients with MPS II

On July 23, 2014, Shire announced a worldwide licensing and collaboration agreement with ArmaGen for SHP631 (also known as AGT-182). SHP631 is an investigational enzyme replacement therapy for the potential treatment of both the central nervous system and somatic manifestations in patients with MPS II. SHP631 is designed to take advantage of the body's natural system for transporting products across the blood brain barrier by using the same receptor that delivers insulin to the brain. SHP631 has received Orphan Drug designation from both the FDA and the EMA. In the second quarter of 2015, ArmaGen initiated a Phase 1 sequential, open-label, dose escalation, multi-dose study in adults with Hunter syndrome. At least two dose levels, assuming tolerability, are planned sequentially, and the trial is expected to deliver information on the possible effect of SHP631 on CSF levels of glycosaminoglycan substrate, which will be important in determining the next steps in clinical development.

Other development projects

A number of additional early development projects, focused on rare diseases, are underway in various stages of pre-clinical development.

On January 22, 2016 Shire acquired Dyax's pipeline portfolio comprising SHP643 for the treatment of HAE, as outlined above, and a number of other programs at various stages of development.

Results of operations for the three months ended March 31, 2016 and 2015

- Total product sales were up 14% on Q1 2015 (up 16% on a Non GAAP CER¹ basis) to \$1,627 million (2015: \$1,423 million), with strong revenue growth from VYVANSE (up 22% to \$509 million), LIALDA/MEZAVANT (up 13% to \$168 million), CINRYZE (up 11% to \$164 million), FIRAZYR (up 39% to \$128 million) and GATTEX/REVESTIVE (up 97% on a pro-forma basis⁽²⁾ to \$52 million).
- Royalties and other revenues were up 26% to \$82 million, as Q1 2016 benefited from a full quarter of SENSIPAR royalties acquired with NPS.
- Operating income was up 15% to \$544 million (2015: \$475 million) primarily due to the increase in total revenue, offset by the inclusion of higher amortization expense related to the intangible assets acquired with Dyax and NPS, and higher acquisition costs primarily related to the announced combination with Baxalta. R&D and SG&A expenditure also increased compared to Q1 2015 due to continued investment in the existing pipeline and increased marketing spend for the anticipated lifitegrast launch (which remains subject to regulatory approval).
- Diluted earnings per ordinary share increased 2% to \$0.71 (2015: \$0.69) primarily due to higher operating income, partially offset by an increase in interest expense and higher effective tax rate.

⁽¹⁾ The Company's management analyzes product sales and revenue growth for certain products sold in markets outside of the US on a constant exchange rate ("CER") basis, so that product sales and revenue growth can be considered excluding movements in foreign exchange rates. Product sales and revenue growth on a CER basis is a Non GAAP financial measure ("Non GAAP CER"), computed by comparing 2016 product sales and revenues restated using 2015 average foreign exchange rates to 2015 actual product sales and revenues. Average exchange rates used by Shire for the first quarter of 2016 were \$1.43:£1.00 and \$1.09:€1.00 (2015: \$1.54:£1.00 and \$1.15:€1.00).

⁽²⁾ Sales prior to February 21, 2015 were recorded by NPS.

Results of operations for the three months ended March 31, 2016 and 2015

Total revenues

The following table provides an analysis of the Company's total revenues by source:

	3 Months Ended March 31,		
	2016	2015	change
	\$'M	\$'M	%
Product sales	1,627.3	1,423.2	+14
Royalties	79.2	62.8	+26
Other revenues	2.8	2.4	+17
Total	1,709.3	1,488.4	+15

Product sales

The following table provides an analysis of the Company's key product sales:

Net product sales:	3 Months Ended March 31,		Product sales growth %	Non-GAAP CER growth %	US prescription growth ¹ %	Exit market share ¹ %
	2016 \$'M	2015 \$'M				
VYVANSE	509.2	416.8	+22	+23	+10	17
LIALDA/MEZAVANT	168.0	148.5	+13	+14	+12	38
CINRYZE	164.2	148.1	+11	+11	n/a ²	n/a ²
FIRAZYR	128.3	92.5	+39	+40	n/a ²	n/a ²
ELAPRASE	123.6	125.0	-1	+4	n/a ²	n/a ²
REPLAGAL	103.2	97.5	+6	+12	n/a ³	n/a ³
ADDERALL XR	98.8	95.7	+3	+4	+6	5
VPRIV	83.6	86.4	-3	-	n/a ²	n/a ²
PENTASA	64.0	78.7	-19	-19	-8	12
GATTEX/REVESTIVE	51.7	14.9	+247 ⁴	+249	n/a ²	n/a ²
FOSRENOL	37.7	44.1	-15	-12	n/a ²	n/a ²
XAGRID	28.3	25.3	+12	+8	n/a ²	n/a ²
NATPARA	15.6	-	n/a	n/a	n/a ²	n/a ²
KALBITOR	10.4	-	n/a	n/a	n/a ²	n/a ²
INTUNIV	10.2	17.4	-41	-39	-67	<1
Other product sales	30.5	32.3	-6	+5	n/a	n/a
Total product sales	1,627.3	1,423.2	+14			

(1) This information is an estimate derived from the use of information under license from the following IMS Health information service: IMS NPA Weekly ("IMS NPA") for the period January 1, 2015 to March 31, 2016. IMS expressly reserves all rights, including rights of copying, distribution and republication.

(2) IMS NPA Data not available.

(3) Not sold in the US in the first quarter of 2016.

(4) Product sales increased 97% on a pro-forma basis. Sales prior to February 21, 2015 were recorded by NPS, prior to the acquisition by Shire.

VYVANSE – ADHD and BED

VYVANSE product sales increased 22% (up 23% on a Non GAAP CER basis) in Q1 2016 compared to Q1 2015. The increase was driven by year over year prescription growth in the US (up 10%), the benefit of price increases¹ taken since Q1 2015 and, to a lesser extent, growth in our international markets. These growth factors were partially offset by higher sales deductions in Q1 2016 compared to the same period in the prior year.

Litigation proceedings regarding VYVANSE are ongoing. For detailed information about this litigation please see Note 15, Commitments and Contingencies - Legal and other proceedings to the Consolidated Financial Statements set forth in this Quarterly Report on Form 10-Q.

LIALDA/MEZAVANT – Ulcerative Colitis

Product sales for LIALDA/MEZAVANT in Q1 2016 increased 13% (up 14% on a Non GAAP CER basis) compared to Q1 2015. The benefit of higher prescription demand and a price increase¹ taken since Q1 2015 was partially offset by higher sales deductions in Q1 2016 compared to Q1 2015.

Litigation proceedings regarding LIALDA/MEZAVANT are ongoing. For detailed information about this litigation please see Note 15, Commitments and Contingencies - Legal and other proceedings to the Unaudited Consolidated Financial Statements set forth in this Quarterly Report on Form 10-Q.

CINRYZE – for the prophylactic treatment of HAE

CINRYZE sales were up 11% (up 11% on a Non GAAP CER basis), primarily driven by strong growth in patients on therapy and higher utilization per patient in Q1 2016.

FIRAZYR – for the treatment of acute HAE attacks

FIRAZYR product sales were up 39% (up 40% on a Non GAAP CER basis), primarily due to growth in patients on therapy, higher utilization per patient and, to a lesser extent, price increases¹ taken since Q1 2015.

ELAPRASE – Hunter syndrome

ELAPRASE product sales in Q1 2016 were down 1% compared to Q1 2015, reflecting the negative impact of foreign exchange movements. On a Non GAAP CER basis, ELAPRASE sales increased 4% compared to Q1 2015 due to an increase in the number of patients.

REPLAGAL – Fabry disease

REPLAGAL sales in Q1 2016 were up 6% compared to Q1 2015, reflecting a higher number of patients on therapy and a shipment in Q1 2016 to a market that orders less frequently. On a Non GAAP CER basis, REPLAGAL sales in Q1 2016 were up 12% compared to Q1 2015.

ADDERALL XR – ADHD

ADDERALL XR product sales were up 3% in Q1 2016 (up 4% on a Non GAAP CER basis), as increased prescription demand and higher stocking in the quarter more than offset the effect of higher sales deductions as a percentage of product sales in Q1 2016 compared to Q1 2015.

VPRIV – Gaucher disease

VPRIV product sales in Q1 2016 were down 3% (flat on a Non GAAP CER basis) as sales growth continued to be negatively impacted by foreign exchange rates and the impact of new competition in the US market.

PENTASA – Ulcerative Colitis

PENTASA product sales were down 19% (down 19% on a Non GAAP CER basis) in Q1 2016 driven by reduced prescription demand and destocking in Q1 2016 compared to stocking in Q1 2015.

GATTEX/REVESTIVE – Short Bowel Syndrome

Product sales increased to \$52 million in Q1 2016 (up 97% on a pro-forma basis⁽²⁾).

NATPARA – Hypoparathyroidism

NATPARA was launched on April 1, 2015. During Q1 2016, Shire recognized \$16 million of product sales.

KALBITOR – for the treatment of acute HAE attacks

On January 22, 2016 Shire acquired KALBITOR through its acquisition of Dyax, and recorded sales of \$10 million for the period subsequent to acquisition.

INTUNIV – ADHD

INTUNIV product sales decreased 41% (down 39% on a Non GAAP CER basis) in Q1 2016 compared to Q1 2015 reflecting the continued impact of generic competitors, which has reduced the Company's market share. Generic competition began in December 2014.

(1) The actual net effect of price increases on current period net sales compared to the comparative period is difficult to quantify due to the various managed care rebates, Medicaid discounts, other discount programs in which the Company participates and fee for service agreements with wholesalers customers.

(2) Sales prior to February 21, 2015 were recorded by NPS, prior to the acquisition by Shire.

Royalties

The following table provides an analysis of Shire's royalty income:

	3 Months Ended March 31,		
	2016	2015	Change
	\$'M	\$'M	%
SENSIPAR	37.9	10.4	264% ¹
3TC and ZEFFIX	15.0	7.5	100%
FOSRENOL	9.2	8.4	10%
INTUNIV	-	21.7	n/a
ADDERALL XR	5.8	8.5	-32%
Other	11.3	6.3	79%
Total royalties	79.2	62.8	26%

(1) Up 40% on a pro-forma basis. Royalties prior to February 21, 2015 were recorded by NPS.

Royalty income increased 26% in Q1 2016 compared to Q1 2015 primarily due to SENSIPAR. Shire acquired royalty rights to SENSIPAR as part of its acquisition of NPS, which closed February 21, 2015. Other royalties in Q1 2015 included \$22 million of INTUNIV royalties that did not continue in 2016.

Cost of product sales

Cost of product sales increased to \$248.6 million for the three months ended March 31, 2016 (15% of product sales), from \$227.8 million in the corresponding period in 2015 (16% of product sales). Cost of product sales as a percentage of product sales decreased by 1 percentage point in the first quarter of 2016 compared to the same period in 2015 related to AbbVie's terminated offer and higher depreciation in the first quarter of 2015.

For the three months ended March 31, 2016 cost of product sales included depreciation of \$8.3 million (2015: \$11.7 million).

R&D

R&D expenditure increased by 12% to \$217.1 million for the three months ended March 31, 2016 (13% of product sales), compared to \$193.7 million in the corresponding period in 2015 (14% of product sales). The first quarter of 2015 included costs of \$5.8 million associated with AbbVie's terminated offer for Shire. Excluding these costs, R&D expenditure for the three months ended March 31, 2016 was 16% higher than the corresponding period in 2015, due to continued investment in existing pipeline programs including SHP465 and additional R&D expenses not incurred in the first quarter of 2015 related to programs acquired as part of the acquisitions of NPS and Dyax.

For the three months ended March 31, 2016 R&D included depreciation of \$5.9 million (2015: \$2.8 million).

SG&A

SG&A expenditure increased by 20% to \$609.5 million (37% of product sales) from \$506.6 million (36% of product sales). The first quarter of 2015 included costs of \$13.5 million associated with AbbVie's terminated offer for Shire. Excluding these costs, SG&A expenditure for the three months ended March 31, 2016 was 24% higher than the corresponding period in 2015, due to higher amortization charges on intangible assets acquired with NPS and Dyax and higher marketing spend in support of the anticipated Lifitegrast launch and ongoing GATTEX launches.

For the three months ended March 31, 2016 SG&A included depreciation of \$20.1 million (2015: \$17.8 million) and amortization of \$134.6 million (2015: \$88.3 million).

Reorganization costs

For the three months ended March 31, 2016 Shire recorded reorganization costs of \$3.3 million (2015: \$15.2 million), primarily related to the relocation of roles to Lexington, Massachusetts from Chesterbrook, Pennsylvania and established Lexington as the Company's US operational headquarters.

Integration and acquisition costs

For the three months ended March 31, 2016 Shire recorded integration and acquisition costs of \$91.1 million, primarily related to integration and acquisition activities related to Dyax and costs associated with the proposed combination with Baxalta.

For the three months ended March 31, 2015 Shire recorded integration and acquisition costs of \$75.7 million primarily related to the acquisition and integration of NPS.

Interest expense

Shire incurred interest expense of \$44.7 million for the three months ended March 31, 2016, primarily related to the interest and amortization of financing fees incurred on borrowings to fund the Dyax acquisition and the amortization of one time upfront arrangement fees incurred on borrowings associated with the proposed business combination with Baxalta.

Interest expense of \$9.6 million in the first quarter of 2015 primarily related to interest and amortization of fees incurred on borrowings to fund the NPS acquisition.

Taxation

The effective tax rate on income from continuing operations in the first quarter of 2016 was 17% (2015: 12%).

The effective tax rate in the first quarter of 2016 on income from continuing operations is higher than the same period in 2015 primarily due to the adverse impact in the first quarter of 2016 of the one-time re-measurement of deferred tax as a result of the Dyax acquisition and the benefit of the favorable re-measurement of uncertain tax positions in the first quarter of 2015.

Discontinued operations

The gain from discontinued operations for the three months ended March 31, 2016 was \$9.5 million, net of tax (2015: \$2.5 million loss, net of tax) primarily related to reimbursement of legal costs associated with the divested DERMAGRAFT business.

Financial condition at March 31, 2016 and December 31, 2015

Cash & cash equivalents

Cash and cash equivalents decreased by \$66.5 million to \$69.0 million as of March 31, 2016 (December 31, 2015: \$135.5 million), primarily due to the use of existing cash and cash equivalents to partially fund the acquisition of Dyax, higher payments for taxes and interest, offset by strong cash receipts from higher sales.

Accounts receivable, net

Accounts receivable, net increased by \$111.5 million to \$1,312.7 million as of March 31, 2016 (December 31, 2015: \$1,201.2 million), primarily due to an increase in revenue. Days sales outstanding increased to 45 days (December 31, 2015: 42 days).

Inventories

Inventories increased by \$44.6 million to \$680.0 million as of March 31, 2016 (December 31, 2015: \$635.4 million), primarily due to the inventories acquired as part of the acquisition of Dyax and an increase in inventories of certain products following continued sales growth.

Goodwill

Goodwill increased by \$2,734.1 million to \$6,881.9 million as of March 31, 2016 (December 31, 2015: \$4,147.8 million), principally due to the acquisition of Dyax.

Other intangible assets, net

Other intangible assets increased by \$4,542.3 million to \$13,715.6 million as of March 31, 2016 (December 31, 2015: \$9,173.3 million), principally due to the intangible assets acquired with Dyax.

Short term borrowings

Short term borrowings increased by \$699.8 million to \$2,211.3 million as of March 31, 2016 (December 31, 2015: \$1,511.5 million), primarily reflecting the utilization of short term debt facilities and RCF to partially fund the acquisition of Dyax.

Long term borrowings

Long term borrowings increased by \$4,584.1 million to \$4,654.0 million as of March 31, 2016 (December 31, 2015: \$69.9 million), reflecting the utilization of the November 2015 Facilities Agreement to fund the acquisition of Dyax.

Non-current deferred tax liabilities

Non-current deferred tax liabilities increased by \$1,337.4 million to \$3,543.3 million at March 31, 2016 (December 31, 2015: \$2,205.9 million) primarily due to the Dyax acquisition including establishing deferred tax liabilities for the acquired intangible assets partially offset by acquired deferred tax assets.

Other non-current liabilities

Other non-current liabilities increased by \$417.9 million to \$1,216.7 million at March 31, 2016 (December 31, 2015: \$798.8 million) principally due to the recognition of contingent consideration payable related to the acquisition of Dyax.

Liquidity and capital resources

General

The Company's funding requirements depend on a number of factors, including the timing and extent of its development programs; corporate, business and product acquisitions; the level of resources required for the expansion of certain manufacturing and marketing capabilities as the product base expands; increases in accounts receivable and inventory which may arise with any increase in product sales; technological developments; the timing and cost of obtaining required regulatory approvals for new products; the timing and quantum of milestone payments on business combinations, in-licenses and collaborative projects; the timing and quantum of tax and dividend payments; the timing and quantum of purchases by the Employee Benefit Trust of Shire shares in the market to satisfy awards granted under Shire's employee share plans; and the amount of cash generated from sales of Shire's products and royalty receipts.

An important part of Shire's business strategy is to protect its products and technologies through the use of patents, proprietary technologies and trademarks, to the extent available. The Company intends to defend its intellectual property and as a result may need cash for funding the cost of litigation.

The Company finances its activities through cash generated from operating activities; credit facilities; private and public offerings of equity and debt securities; and the proceeds of asset or investment disposals.

Shire's balance sheet includes \$69.0 million of cash and cash equivalents at March 31, 2016.

Shire has a revolving credit facility of \$2,100 million which matures in 2020, \$1,210 million of which was utilized as of March 31, 2016. The RCF incorporates a \$250 million US dollar and Euro swingline facility operating as a sub-limit thereof.

As of March 31, 2016, in connection with the acquisition of Dyax and the proposed combination with Baxalta, Shire entered into a \$5,600 million term loan facility in November 2015 and an \$18,000 million bridge loan in January 2016. The details of these facility agreements are presented in Note 13, Borrowings, to these Unaudited Consolidated Financial Statements.

In addition, Shire has access to certain short-term uncommitted lines of credit which are available to utilize from time to time to provide short-term cash management flexibility. As of March 31, 2016, these lines of credit were not utilized.

Financing

Shire anticipates that its operating cash flow together with available cash, cash equivalents and the RCF will be sufficient to meet its anticipated future operating expenses, capital expenditures, tax and interest payments, lease obligations, repayment of the term loans and milestone payments as they become due over the next twelve months.

Shire's existing cash, the January 2016 Facilities Agreement and the RCF are sufficient to finance Shire's proposed combination with Baxalta.

If the Company decides to acquire other businesses, it expects to fund these acquisitions from cash resources, the RCF and through new borrowings (including issuances of debt securities) or the issuance of new equity if necessary.

Sources and uses of cash

The following table provides an analysis of the Company's gross and net debt position (excluding restricted cash), as of March 31, 2016 and December 31, 2015:

	March 31, 2016 \$'M	December 31, 2015 \$'M
Cash and cash equivalents ¹	69.0	135.5
Long term borrowings	(4,654.0)	(69.9)
Short term borrowings	(2,211.3)	(1,511.5)
Other debt	(12.7)	(13.4)
Total debt	(6,878.0)	(1,594.8)
Net debt ²	(6,809.0)	(1,459.3)

- (1) Substantially all of the Company's cash and cash equivalents are held by foreign subsidiaries (i.e, those subsidiaries incorporated outside of Jersey, Channel Islands, the jurisdiction of incorporation of Shire plc, Shire's holding company). The amount of cash and cash equivalents held by foreign subsidiaries has not had, and is not expected to have, a material impact on the Company's liquidity and capital resources.
- (2) Net debt is a Non-GAAP measure. Net debt represents US GAAP cash and cash equivalents less US GAAP short and long term borrowings and other debt (see above). The Company believes that Net debt is a useful measure as it indicates the level of borrowings after taking account the cash and cash equivalents that could be utilized to pay down the outstanding borrowings.

Cash flow activity

Net cash provided by operating activities in the three months ended March 31, 2016 decreased by \$172.1 million or 31% to \$389.5 million (2015: \$561.6 million), primarily due to higher payments for taxes in the first quarter of 2016 compared to the benefit of a tax repayment in the first quarter of 2015, and higher interest payments due to the utilization of debt facilities to partially fund the acquisition of Dyax, offset by strong cash receipts from higher revenues in the first quarter of 2016.

Net cash used in investing activities was \$5,674.1 million in the three months ended March 31, 2016, principally relating to the cash paid for the acquisition of Dyax (\$5,934 million, less cash acquired with Dyax of \$241 million).

Net cash used in investing activities was \$5,177.2 million in the three months ended March 31, 2015, principally relating to the cash paid for the acquisition of NPS of \$5,125 million (less cash acquired with NPS of \$42 million) and for the acquisition of Meritage of \$75 million.

Net cash provided by financing activities was \$5,217.1 million for the three months ended March 31, 2016, principally due to the drawings, net of subsequent repayments, made under Shire's RCF and November 2015 Facilities Agreement to partially fund the Dyax acquisition.

Net cash provided by financing activities was \$1,709.1 million for the three months ended March 31, 2015, principally due to the drawings, net of subsequent repayments, made under Shire's RCF and January 2015 Facilities Agreement to partially fund the NPS acquisition.

Obligations and commitments

Other than the borrowings incurred to finance or assumed following the acquisition of Dyax, as outlined above, during the three months ended March 31, 2016 there have been no material changes to the Company's contractual obligations previously disclosed in PART II: ITEM 7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Note 17 to the Unaudited Consolidated Financial Statements included in PART I: ITEM 1 of this Form 10-Q and PART II: ITEM 7A of the Company's Annual Report on Form 10-K for the year ended December 31, 2015 contains a discussion of the Company's exposure to market and other risks.

ITEM 4. CONTROLS AND PROCEDURES

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports that the Company files under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC.

As of March 31, 2016 the Company, under the supervision and with the participation of the Company's management, including the Chief Executive Officer and the Chief Financial Officer, performed an evaluation of the effectiveness of the Company's disclosure controls and procedures, including those with respect to the Income Access Share ("IAS") Trust. The Company's management necessarily applied its judgment in assessing the costs and benefits of such controls and procedures, which by their nature can provide only reasonable assurance regarding management's control objectives. Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures, including those with respect to the IAS Trust, are effective at the reasonable level of assurance to ensure that information required to be disclosed in reports that the Company files under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC.

There has been no change in the Company's internal control over financial reporting that occurred during the period covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information required by this Item is incorporated herein by reference to Note 15 to the Unaudited Consolidated Financial Statements included in PART I: ITEM 1 of this Form 10-Q.

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

EXHIBITS

- 2.01 Agreement and Plan of Merger dated as of January 11, 2016 among Shire plc, Bear Tracks, Inc. and Baxalta Incorporated. ⁽¹⁾
- 3.01 Articles of Association of Shire plc as amended by a special resolution passed on April 28, 2016 and adopted by a special resolution passed on April 28, 2016. ⁽²⁾
- 10.01 Letter Agreement among Shire plc, Baxalta Incorporated and Baxter International Inc. dated January 11, 2016. ⁽¹⁾
- 10.02 Bridge Facilities Agreement among Shire plc, Barclays Bank plc and Morgan Stanley Bank International Limited dated January 11, 2016. ⁽¹⁾
- 10.03 Contingent Value Rights Agreement by and between Shire plc and American Stock Transfer & Trust Company, LLC dated as of January 22, 2016. ⁽³⁾
- 31.1 Certification of Flemming Ormskov pursuant to Rule 13a - 14 under The Exchange Act.
- 31.2 Certification of Jeffrey Poulton pursuant to Rule 13a - 14 under The Exchange Act.
- 32.1 Certification of Flemming Ormskov and Jeffrey Poulton pursuant to Section 906 of the Sarbanes - Oxley Act of 2002.
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Definition Linkbase Document
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document
- (1) Incorporated by reference to Exhibit 2.1 to Shire's Form 8-K filed on January 11, 2016.
- (2) Incorporated by reference to Exhibit 3.1 to Shire's Form 8-K filed on April 29, 2016.
- (3) Incorporated by reference to Exhibit 10.1 to Shire's Form 8-K filed on January 22, 2016.

SIGNATURES

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

Date: May 4, 2016

/s/ Flemming Omskov
Flemming Omskov
Chief Executive Officer

Date: May 4, 2016

/s/ Jeffrey Poulton
Jeffrey Poulton
Chief Financial Officer

**CERTIFICATION OF FLEMMING ORNSKOV PURSUANT TO
RULE 13A-14 UNDER THE
SECURITIES EXCHANGE ACT OF 1934
FORM 10-Q FOR THE QUARTER ENDED
MARCH 31, 2016 OF
SHIRE PLC**

I, Flemming Ornskov, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Shire plc;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d - 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d - 15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2016

/s/ Flemming Ornskov
Flemming Ornskov
Chief Executive Officer

**CERTIFICATION OF JEFFREY POULTON PURSUANT TO
RULE 13A-14 UNDER THE
SECURITIES EXCHANGE ACT OF 1934
FORM 10-Q FOR THE QUARTER ENDED
MARCH 31, 2016 OF
SHIRE PLC**

I, Jeffrey Poulton, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Shire plc;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d - 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d - 15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2016

/s/ Jeffrey Poulton
Jeffrey Poulton
Chief Financial Officer

The certification set forth below is being submitted in connection with the Quarterly Report on Form 10-Q of Shire plc for the quarter ended March 31, 2016 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

Flemming Ornskov, the Chief Executive Officer and Jeffrey Poulton, the Chief Financial Officer of Shire plc, each certifies that, to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Shire plc.

Date: May 4, 2016

/s/ Flemming Ornskov
Flemming Ornskov
Chief Executive Officer

/s/ Jeffrey Poulton
Jeffrey Poulton
Chief Financial Officer
