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FORM 8-K

Shire plc - N/A

Filed: April 29, 2016 (period: April 29, 2016)

Report of unscheduled material events or corporate changes.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 29, 2016

Shire plc

(Exact name of registrant as specified in its charter)

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

0-29630
(Commission File Number)

98-0601486
(IRS Employer Identification No.)

5 Riverwalk, Citywest Business Campus, Dublin
24, Republic of Ireland

(Address of principal executive offices) (Zip code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2.):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 2.02. Results of Operations and Financial Condition

On April 29, 2016, Shire plc issued a press release announcing its financial results for the three month period ended March 31, 2016 which is attached hereto as Exhibit 99.1 and incorporated by reference herein. The information furnished pursuant to this Item 2.02, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits. The following exhibit is furnished herewith:

99.1 Press Release dated April 29, 2016

SIGNATURE

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

SHIRE PLC

By: /s/ B Mordan

Name: Bill Mordan

Title: Company Secretary

Dated: April 29, 2016

EXHIBIT INDEX

Number	Description
99.1	Press Release dated April 29, 2016

Press Release



Shire delivers strong Q1 2016 results with double-digit growth in revenue and Non GAAP earnings per ADS

Proposed combination with Baxalta on track with shareholder votes set for May 27 and closing anticipated in early June 2016

April 29, 2016 – Shire plc (“Shire”) (LSE: SHP, NASDAQ: SHPG) announces unaudited results for the three months ended March 31, 2016.

Financial Highlights	Q1 2016	Growth ⁽¹⁾	Non GAAP CER ⁽¹⁾⁽²⁾
Product sales	\$1,627 million	+14%	+16%
Total revenues	\$1,709 million	+15%	+17%
Non GAAP operating income	\$797 million	+17%	+16%
US GAAP operating income from continuing operations	\$544 million	+15%	
Non GAAP EBITDA margin (excluding royalties & other revenues) ⁽³⁾	46%	0pps ⁽⁴⁾	
US GAAP net income margin ⁽⁵⁾	25%	-3pps	
Non GAAP net income	\$632 million	+13%	
US GAAP net income	\$419 million	+2%	
Non GAAP diluted earnings per ADS	\$3.19	+12%	+12%
US GAAP diluted earnings per ADS	\$2.12	+2%	
Non GAAP cash generation	\$492 million	-5%	
Non GAAP free cash flow	\$338 million	-38%	
US GAAP net cash provided by operating activities	\$390 million	-31%	

⁽¹⁾ Percentages compare to equivalent 2015 period.

⁽²⁾ On a Constant Exchange Rate (“CER”) basis, which is a Non GAAP measure.

⁽³⁾ Non GAAP earnings before interest, tax, depreciation and amortization (“EBITDA”) as a percentage of product sales, excluding royalties and other revenues.

⁽⁴⁾ Percentage point change (“pps”).

⁽⁵⁾ US GAAP net income as a percentage of total revenues.

The Non GAAP financial measures included within this release are explained on pages 25 - 26, and are reconciled to the most directly comparable financial measures prepared in accordance with US GAAP on pages 19 - 22.

First Quarter & Recent Highlights:

- Product sales growth of 14% (16% on a Non GAAP CER basis) to \$1.6 billion, driven by VYVANSE®, LIALDA®/MEZAVANT®, CINRYZE®, FIRAZYR®, GATTEX®/REVESTIVE® and NATPARA®.
- Rare disease products acquired from NPS Pharmaceuticals, Inc. (“NPS”) continued to perform well with GATTEX/REVESTIVE sales up 247% (up 97% on a pro-forma basis⁽¹⁾) to \$52 million, and NATPARA sales of \$16 million.
- Free cash flow remained strong, impacted primarily by net payments and receipts of taxes between Q1 2015 and Q1 2016.
- Lifitegrast New Drug Application (“NDA”) accepted by the US Food and Drug Administration (“FDA”), with Prescription Drug User Fee Act (“PDUFA”) date set for July 22, 2016.
- Pipeline progression with positive topline results from SHP465 safety and efficacy study in children and adolescents with Attention Deficit Hyperactivity Disorder (“ADHD”).
- Completed acquisition of Dyax Corp. (“Dyax”) and enrollment on track for SHP643 (formerly DX2930) Phase 3 studies for the treatment of Hereditary Angioedema (“HAE”).
- Patent upheld for LIALDA (mesalamine) delayed release tablets by U.S. District Court for the Southern District of Florida; the case has been appealed.
- Baxalta Incorporated (“Baxalta”) acquisition on track with integration progressing well; shareholder votes set for May 27 and closing anticipated in early June.

⁽¹⁾ Sales prior to February 21, 2015 were recorded by NPS.

Registered in Jersey, No. 99854, 22 Grenville Street, St Helier, Jersey JE4 8PX

Flemming Ornskov, M.D. Chief Executive Officer, commented:

“Shire is off to a strong start in 2016, delivering double-digit product sales and Non GAAP earnings per ADS growth, and advancing our innovative pipeline. We were pleased to report positive Phase 3 topline results for SHP465 in children and adolescents with ADHD, a therapeutic area with significant need for additional treatment options. We are also looking forward to hearing from the FDA by late July regarding lifitegrast, a potential new treatment for dry eye disease.

While we maintain our sharp focus on Shire's business, we closed the acquisition of Dyax during the quarter and we are making excellent progress with the Baxalta integration planning. Our shareholder vote is scheduled for May 27 and the closing is anticipated to follow in early June. We look forward to officially welcoming our Baxalta colleagues to Shire, and creating a global biotechnology leader focused on rare diseases and other highly specialized conditions.”



FINANCIAL SUMMARY

First Quarter 2016 Unaudited Results

- Total product sales were up 14% on Q1 2015 (up 16% on a Non GAAP CER basis) at \$1,627 million (Q1 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⁽¹⁾ 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.
- On a Non GAAP basis:

Operating income increased 17% to \$797 million (Q1 2015: \$683 million) as combined Research & Development expenditure ("R&D") and Selling, General and Administrative expenditure ("SG&A") (up 14%) grew at a slower rate than total revenues. R&D increased by 14% compared to Q1 2015 due to the inclusion of Dyax operating costs and continued investment in the existing pipeline. SG&A increased by 14%, primarily due to the inclusion of Dyax operating costs and increased marketing spend for the anticipated lifitegrast launch (which remains subject to regulatory approval).

Non GAAP EBITDA margin (excluding royalties and other revenues) was 46%, consistent with the margin achieved in Q1 2015.

On a US GAAP basis (from continuing operations):

Operating income was up 15% to \$544 million (Q1 2015: \$475 million). US GAAP operating income growth in Q1 2016 was lower than Non GAAP operating income due to 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.

- Non GAAP diluted earnings per American Depositary Share ("ADS") increased 12% to \$3.19 (Q1 2015: \$2.84), primarily due to higher Non GAAP operating income, partially offset by higher interest expense.

On a US GAAP basis diluted earnings per ADS increased 2% to \$2.12 (Q1 2015: \$2.08), primarily due to higher US GAAP operating income, partially offset by an increase in interest expense and higher effective tax rate on US GAAP income.

- Cash generation, a Non GAAP measure, was down 5% to \$492 million compared to \$516 million in Q1 2015, primarily due to higher integration and acquisition costs for Dyax and Baxalta and the timing of payments of accounts payable, offset by strong cash receipts from higher sales.

Free cash flow, a Non GAAP measure, was down 38% to \$338 million (Q1 2015: \$542 million), primarily due to lower cash generation and higher payments for taxes in Q1 2016 compared to the benefit of a tax repayment in Q1 2015, an increase in capital expenditures, and higher interest payments.

On a US GAAP basis, net cash provided by operating activities was down 31% to \$390 million (Q1 2015: \$562 million), primarily due to lower cash generation and higher payments for taxes in Q1 2016 compared to the benefit of a tax repayment in Q1 2015, and higher interest payments.

Net debt, a Non GAAP measure, at March 31, 2016 was \$6,809 million (December 31, 2015: \$1,459 million) reflecting the use of cash and cash equivalents and borrowings incurred to fund the acquisition of Dyax.

⁽¹⁾ Sales prior to February 21, 2015 were recorded by NPS.

OUTLOOK

We are off to a strong start in 2016 and reiterate our previously announced 2016 guidance. The guidance provided excludes the effect of the anticipated combination with Baxalta which is expected to close in June.

We continue to expect product sales to increase by 11% to 14% on a reported basis in 2016, and increase approximately 13% to 17% on a Non GAAP CER basis.

Royalties and other revenues are expected to increase by 5% to 10% in 2016, primarily from the benefit of a full year of the SENSIPAR royalty stream acquired as part of the NPS transaction and royalties acquired as part of the Dyax transaction.

Our Non GAAP gross margin is expected to be in line with 2015 (2015: 85.5%).

We expect our combined Non GAAP R&D and SG&A costs to increase in the 12% to 14% range as we absorb the operating costs associated with the Dyax transaction, make commercial investments to support our anticipated launch of lifitegrast in the second half of this year and progress our pipeline, particularly the programs in late-stage clinical development.

As a result of funding the Dyax transaction with a \$5.6 billion term loan bank facility, we expect our Non GAAP net interest and other expense to increase by approximately 1.5 to 2 times 2015 levels (2015: \$49 million).

For 2016, we expect our effective tax rate on Non GAAP income to be in the range of 16% to 18%.

For Non GAAP diluted earnings per ADS, we expect 2016 growth in the 7% to 10% range (9% to 13% on a Non GAAP CER basis).



FIRST QUARTER 2016 AND RECENT PRODUCT AND PIPELINE 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 ADHD and Binge Eating Disorder ("BED") in adults

- An 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 SHP465 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. 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 were also 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. Integration planning is on track and is ahead of other deals of this size, according to a 2016 McKinsey analysis from Deal Logic for transactions of over \$5 billion in value (January 2009 to April 2015).

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 DX2930), 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 U.S. 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. ("Watson") proposed abbreviated new drug application product infringes the patent-in-suit. Watson appealed the ruling to the U.S. Court of Appeals of the Federal Circuit.

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.



ADDITIONAL INFORMATION

The following additional information is included in this press release:

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Dial in details for the **live conference call** for investors at 14:00 BST / 09:00 EDT on April 29, 2016:

UK dial in:	0808 237 0030 or 020 3139 4830
US dial in:	1 866 928 7517 or 1 718 873 9077
International Access Numbers:	Click here
Password/Conf ID:	76461165#
Live Webcast:	Click here

The quarterly earnings presentation will be available today at 12:00 BST / 07:00 EDT on:

- Shire.com [Investors section](#)
- Shire's IR Briefcase in the [iTunes Store](#)



OVERVIEW OF FIRST QUARTER 2016 FINANCIAL RESULTS

1. Product sales

For the three months ended March 31, 2016 product sales were up 14% to \$1,627 million (Q1 2015: \$1,423 million) and represented 95% of total revenues (Q1 2015: 96%).

Product sales	Sales \$M	Year on year growth			US Exit Market Share ⁽²⁾
		Sales	Non GAAP CER ⁽¹⁾	US Rx ⁽²⁾	
VYVANSE	509.2	+22%	+23%	+10%	17%
LIALDA/MEZAVANT	168.0	+13%	+14%	+12%	38%
CINRYZE	164.2	+11%	+11%	n/a ⁽³⁾	n/a ⁽³⁾
FIRAZYR	128.3	+39%	+40%	n/a ⁽³⁾	n/a ⁽³⁾
ELAPRASE [®]	123.6	-1%	+4%	n/a ⁽³⁾	n/a ⁽³⁾
REPLAGAL [®]	103.2	+6%	+12%	n/a ⁽⁴⁾	n/a ⁽⁴⁾
ADDERALL XR [®]	98.8	+3%	+4%	+6%	5%
VPRIV [®]	83.6	-3%	-0%	n/a ⁽³⁾	n/a ⁽³⁾
PENTASA [®]	64.0	-19%	-19%	-8%	12%
GATTEX/REVESTIVE	51.7	+247% ⁽⁵⁾	+250%	n/a ⁽³⁾	n/a ⁽³⁾
NATPARA	15.6	n/a	n/a	n/a ⁽³⁾	n/a ⁽³⁾
KALBITOR [®]	10.4	n/a	n/a	n/a ⁽³⁾	n/a ⁽³⁾
INTUNIV [®]	10.2	-41%	-39%	-67%	<1%
OTHER	96.5	-5%	-1%	n/a	n/a
Total	1,627.3	+14%	+16%		

(1) On a CER basis, which is a Non GAAP measure.

(2) 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.

(3) IMS NPA data not available.

(4) Not sold in the US in Q1 2016.

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

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 increases 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.

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 increase taken since Q1 2015 was partially offset by higher sales deductions in Q1 2016 compared to Q1 2015.

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 increases 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 were up 6% compared to Q1 2015, reflecting a higher number of patients on therapy and the timing of a shipment to a market that orders less frequently. On a Non GAAP CER basis, REPLAGAL sales 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 ⁽¹⁾).

⁽¹⁾ Sales prior to February 21, 2015 were recorded by NPS.

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

Shire acquired KALBITOR through its acquisition of Dyax on January 22, 2016, 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 reflecting the continued impact of generic competitors, which has reduced market share. Generic competition began in December 2014.



2. Royalties

Product	Royalties Income \$M	Year on year growth	
		Royalties	CER
SENSIPAR	37.9	+264% ⁽¹⁾	+264%
FOSRENOL [®]	9.2	+10%	+8%
3TC [®] and ZEFFIX [®]	15.0	+100%	+100%
ADDERALL XR	5.8	-32%	-32%
Other	11.3	-60%	-59%
Total	79.2	+26%	+26%

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.

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

3. Financial details

Cost of product sales

	Q1 2016 \$M	% of product sales	Q1 2015 \$M	% of product sales
Cost of product sales (US GAAP)	248.6	15%	227.8	16%
Unwind of inventory fair value step-up	(12.8)		(11.2)	
Costs of employee retention awards following AbbVie Inc.'s ("AbbVie") terminated offer	-		(2.7)	
Depreciation	(8.3)		(11.7)	
Cost of product sales (Non GAAP)	227.5	14%	202.2	14%

Non GAAP cost of product sales as a percentage of product sales remained constant in Q1 2016.

US GAAP cost of product sales as a percentage of product sales decreased due to the inclusion of AbbVie related costs and higher depreciation in Q1 2015.

R&D

	Q1 2016 \$M	% of product sales	Q1 2015 \$M	% of product sales
R&D (US GAAP)	217.1	13%	193.7	14%
Costs of employee retention awards following AbbVie's terminated offer	-		(5.8)	
Depreciation	(5.9)		(2.8)	
R&D (Non GAAP)	211.2	13%	185.1	13%

Non GAAP R&D increased by \$26.1 million, or 14% in Q1 2016, due to continued investment in existing pipeline programs including SHP465 and additional R&D expenses not incurred in Q1 2015 related to programs acquired as part of the acquisitions of NPS and Dyax.

US GAAP R&D increased by \$23.4 million, or 12%, as Q1 2015 included costs associated with AbbVie's terminated offer for Shire.



SG&A

	Q1 2016	% of product	Q1 2015	
	\$M	sales	\$M	% of product sales
SG&A (US GAAP)	609.5	37%	506.6	36%
Intangible asset amortization	(134.6)		(88.3)	
Legal and litigation costs	(15.0)		(0.8)	
Costs incurred in connection with AbbVie's terminated offer	-		(13.5)	
Depreciation	(20.1)		(17.8)	
SG&A (Non GAAP)	439.8	27%	386.2	27%

Non GAAP SG&A increased by \$53.6 million, or 14%, primarily reflecting marketing spend in support of the anticipated lifitegrast launch and ongoing GATTEX launches.

US GAAP SG&A increased by \$102.9 million, or 20%, primarily as a result of higher amortization charges on intangible assets acquired with NPS and Dyax.

Reorganization costs

In Q1 2016, Shire recorded reorganization costs of \$3.3 million (Q1 2015: \$15.2 million), primarily related to the relocation of roles from Chesterbrook to Lexington.

Integration and acquisition costs

In Q1 2016 Shire recorded integration and acquisition costs of \$91.1 million, primarily related to integration and acquisition costs related to Dyax and costs associated with the proposed combination with Baxalta.

In Q1 2015 Shire recorded integration and acquisition costs of \$75.7 million, primarily related to the acquisition and integration of NPS.

Interest expense

Interest expense increased by \$16.9 million on a Non GAAP basis in Q1 2016, primarily due to interest and amortization of financing fees incurred on borrowings to fund the Dyax acquisition. Interest expense in Q1 2015 primarily related to interest and amortization of fees incurred on borrowings to fund the NPS acquisition.

In Q1 2016 Shire incurred US GAAP interest expense of \$44.7 million (Q1 2015: \$9.6 million), primarily related to the above interest expense and the amortization of one-time upfront arrangement fees incurred on borrowings primarily associated with the proposed business combination with Baxalta.

Taxation

The effective tax rate on Non GAAP income in Q1 2016 was 18% (Q1 2015: 17%), and on a US GAAP basis the effective tax rate was 17% (Q1 2015: 12%).

The effective tax rate in Q1 2016 on Non GAAP income from continuing operations is marginally higher than the same period in 2015, primarily due to the benefit of the favorable re-measurement of uncertain tax positions in Q1 2015.

The effective tax rate in Q1 2016 on US GAAP income from continuing operations is higher than the same period in 2015, primarily due to the adverse impact in Q1 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 Q1 2015.

Discontinued operations

The gain from discontinued operations in Q1 2016 was \$9.5 million, net of tax (Q1 2015: \$2.5 million loss, net of tax) primarily related to reimbursement of legal costs associated with the divested DERMAGRAFT business.

FINANCIAL INFORMATION

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Unaudited US GAAP Consolidated Balance Sheets

	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	1,312.7	1,201.2
Inventories	680.0	635.4
Prepaid expenses and other current assets	314.4	197.4
Total current assets	2,398.4	2,255.5
Non-current assets:		
Investments	50.4	50.8
Property, plant and equipment ("PP&E"), net	837.6	828.1
Goodwill	6,881.9	4,147.8
Other intangible assets, net	13,715.6	9,173.3
Deferred tax asset	129.1	121.0
Other non-current assets	42.3	33.3
Total assets	24,055.3	16,609.8
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	1,978.2	2,050.6
Short term borrowings	2,211.3	1,511.5
Other current liabilities	157.1	144.0
Total current liabilities	4,346.6	3,706.1
Non-current liabilities:		
Long term borrowings	4,654.0	69.9
Deferred tax liability	3,543.3	2,205.9
Other non-current liabilities	1,216.7	798.8
Total liabilities	13,760.6	6,780.7
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)	(302.8)	(320.6)
Accumulated other comprehensive loss	(159.4)	(183.8)
Retained earnings	6,190.1	5,788.3
Total equity	10,294.7	9,829.1
Total liabilities and equity	24,055.3	16,609.8



Unaudited US GAAP Consolidated Statements of Income

	3 months ended March 31,	
	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	1,709.3	1,488.4
Costs and expenses:		
Cost of product sales	248.6	227.8
R&D	217.1	193.7
SG&A	609.5	506.6
Gain on sale of product rights	(4.2)	(5.2)
Reorganization costs	3.3	15.2
Integration and acquisition costs	91.1	75.7
Total operating expenses	1,165.4	1,013.8
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	(52.2)	(3.3)
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 tax	409.5	412.9
Gain/(loss) from discontinued operations, net of tax	9.5	(2.5)
Net income	419.0	410.4



Unaudited US GAAP Consolidated Statements of Income (continued)

	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 ADS – basic	\$2.12	\$2.09
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
Earnings per ADS – diluted	\$2.12	\$2.08
Weighted average number of shares:		
	Millions	Millions
Basic	591.7	589.1
Diluted	593.3	592.7



Unaudited US GAAP 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 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 subsidiary undertakings and 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 received on sale of product rights	3.0	3.9
Proceeds from disposal of non-current investments and PP&E	-	0.9
Other, net	2.5	-
Net cash used in investing activities	(5,674.1)	(5,177.2)
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

Selected Notes to the Unaudited US GAAP Financial Statements

(1) Earnings Per Share ("EPS")

	3 months ended March 31,	
	2016	2015
	\$M	\$M
Income from continuing operations	409.5	412.9
Gain/(loss) from discontinued operations	9.5	(2.5)
Numerator for basic and diluted EPS	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

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 Millions	No. of shares Millions
Share based awards to employees	4.0	1.4



Selected Notes to the Unaudited US GAAP Financial Statements

(2) Analysis of revenues

	3 months ended March 31,		2016	2016
	2016	2015	%	% of total
	\$M	\$M	change	revenue
Net product sales:				
VYVANSE	509.2	416.8	22%	30%
LIALDA/MEZAVANT	168.0	148.5	13%	10%
CINRYZE	164.2	148.1	11%	10%
FIRAZYR	128.3	92.5	39%	8%
ELAPRASE	123.6	125.0	-1%	7%
REPLAGAL	103.2	97.5	6%	6%
ADDERALL XR	98.8	95.7	3%	6%
VPRIV	83.6	86.4	-3%	5%
PENTASA	64.0	78.7	-19%	4%
GATTEX/REVESTIVE	51.7	14.9	247%	3%
FOSRENOL	37.7	44.1	-15%	2%
XAGRID	28.3	25.3	12%	2%
NATPARA	15.6	-	n/a	<1%
KALBITOR	10.4	-	n/a	<1%
INTUNIV	10.2	17.4	-41%	<1%
Other product sales	30.5	32.3	-6%	2%
Total product sales	1,627.3	1,423.2	14%	95%
Royalties:				
SENSIPAR	37.9	10.4	264%	2%
3TC and ZEFFIX	15.0	7.5	100%	<1%
FOSRENOL	9.2	8.4	10%	<1%
INTUNIV	-	21.7	n/a	0%
ADDERALL XR	5.8	8.5	-32%	<1%
Other	11.3	6.3	79%	<1%
Total royalties	79.2	62.8	26%	5%
Other revenues	2.8	2.4	17%	<1%
Total revenues	1,709.3	1,488.4	15%	100%

Non GAAP reconciliation for the three months ended March 31, 2016

	US GAAP	Adjustments					Non GAAP
		(a)	(b)	(c)	(d)	(e)	
	\$M	\$M	\$M	\$M	\$M	\$M	\$M
Total revenues	1,709.3	-	-	-	-	-	1,709.3
Costs and expenses:							
Cost of product sales	248.6	-	(12.8)	-	-	(8.3)	227.5
R&D	217.1	-	-	-	-	(5.9)	211.2
SG&A	609.5	(134.6)	-	-	(15.0)	(20.1)	439.8
Gain on sale of product rights	(4.2)	-	-	4.2	-	-	-
Reorganization costs	3.3	-	-	(3.3)	-	-	-
Integration and acquisition costs	91.1	-	(91.1)	-	-	-	-
Depreciation	-	-	-	-	-	34.3	34.3
Total operating expenses	1,165.4	(134.6)	(103.9)	0.9	(15.0)	-	912.8
Operating income	543.9	134.6	103.9	(0.9)	15.0	-	796.5
Interest income	1.0	-	-	-	-	-	1.0
Interest expense	(44.7)	-	18.2	-	-	-	(26.5)
Other expense, net	(8.5)	-	-	6.0	-	-	(2.5)
Total other expense, net	(52.2)	-	18.2	6.0	-	-	(28.0)
Income before income taxes and equity in losses of equity method investees	491.7	134.6	122.1	5.1	15.0	-	768.5
Income taxes	(82.1)	(39.6)	(8.4)	(1.0)	(5.5)	-	(136.6)
Equity in losses of equity method investees, net of tax	(0.1)	-	-	-	-	-	(0.1)
Income from continuing operations	409.5	95.0	113.7	4.1	9.5	-	631.8
Gain from discontinued operations, net of tax	9.5	-	-	(9.5)	-	-	-
Net income	419.0	95.0	113.7	(5.4)	9.5	-	631.8
Weighted average number of shares (millions) – diluted	593.3	-	-	-	-	-	593.3
Diluted earnings per ADS	\$ 2.12	\$ 0.48	\$ 0.57	(\$ 0.03)	\$ 0.05	-	\$ 3.19

The following items are included in Adjustments:

- Amortization and asset impairments: Amortization of intangible assets relating to intellectual property rights acquired (\$134.6 million), and tax effect of adjustments;
- Acquisition and integration activities: Unwind of NPS and Dyax inventory fair value adjustments (\$12.8 million), acquisition and integration costs primarily associated with NPS, Dyax and the proposed combination with Baxalta (\$79.7 million), charges related to the change in fair value of contingent consideration liabilities (\$11.4 million), amortization of one-time upfront arrangement fees incurred on borrowings associated with the proposed combination with Baxalta and the completed acquisition of Dyax (\$18.2 million), and tax effect of adjustments;
- Divestments, reorganizations and discontinued operations: Gain on re-measurement of DAYTRANA contingent consideration to fair value (\$4.2 million), costs relating to the One Shire reorganization, primarily costs relating to the relocation of staff from Chesterbrook to Lexington (\$3.3 million), loss on divestment of non-core subsidiary (\$6.0 million), tax effect of adjustments, and gain from discontinued operations, net of tax (\$9.5 million);
- Legal and litigation costs: Costs related to litigation, government investigations, other disputes and external legal costs (\$15.0 million), and tax effect of adjustments;
- Depreciation reclassification: Depreciation of \$34.3 million included in Cost of product sales, R&D and SG&A for US GAAP separately disclosed for the presentation of Non GAAP earnings.

Non GAAP reconciliation for the three months ended March 31, 2015

	US GAAP	Adjustments						Non GAAP
		(a)	(b)	(c)	(d)	(e)	(f)	
	\$M	\$M	\$M	\$M	\$M	\$M	\$M	\$M
Total revenues	1,488.4	-	-	-	-	-	-	1,488.4
Costs and expenses:								
Cost of product sales	227.8	-	(11.2)	-	-	(2.7)	(11.7)	202.2
R&D	193.7	-	-	-	-	(5.8)	(2.8)	185.1
SG&A	506.6	(88.3)	-	-	(0.8)	(13.5)	(17.8)	386.2
Gain on sale of product rights	(5.2)	-	-	5.2	-	-	-	-
Reorganization costs	15.2	-	-	(15.2)	-	-	-	-
Integration and acquisition costs	75.7	-	(75.7)	-	-	-	-	-
Depreciation	-	-	-	-	-	-	32.3	32.3
Total operating expenses	1,013.8	(88.3)	(86.9)	(10.0)	(0.8)	(22.0)	-	805.8
Operating income	474.6	88.3	86.9	10.0	0.8	22.0	-	682.6
Interest income	2.0	-	-	-	-	(1.1)	-	0.9
Interest expense	(9.6)	-	-	-	-	-	-	(9.6)
Other income, net	4.3	-	-	-	-	-	-	4.3
Total other expense, net	(3.3)	-	-	-	-	(1.1)	-	(4.4)
Income before income taxes and equity								
in losses of equity method investees	471.3	88.3	86.9	10.0	0.8	20.9	-	678.2
Income taxes	(57.4)	(33.1)	(13.6)	(4.4)	(0.4)	(7.8)	-	(116.7)
Equity in losses of equity method investees, net of tax	(1.0)	-	-	-	-	-	-	(1.0)
Income from continuing operations	412.9	55.2	73.3	5.6	0.4	13.1	-	560.5
Loss from discontinued operations, net of tax	(2.5)	-	-	2.5	-	-	-	-
Net income	410.4	55.2	73.3	8.1	0.4	13.1	-	560.5
Weighted average number of shares (millions) – diluted	592.7	-	-	-	-	-	-	592.7
Diluted earnings per ADS	\$ 2.08	\$ 0.28	\$ 0.37	\$ 0.04	\$ -	\$ 0.07	\$ -	\$ 2.84

The following items are included in Adjustments:

- Amortization and asset impairments: Amortization of intangible assets relating to intellectual property rights acquired (\$88.3 million), and tax effect of adjustments;
- Acquisition and integration activities: Unwind of NPS inventory fair value adjustments (\$9.9 million), unwind of ViroPharma inventory fair value adjustments (\$1.3 million), costs primarily associated with the acquisition and integration of NPS (\$69.9 million), costs associated with the integration of ViroPharma (\$3.4 million), net charges related to the change in fair value of contingent consideration liabilities (\$2.4 million), and tax effect of adjustments;
- Divestments, reorganizations and discontinued operations: Gain on re-measurement of DAYTRANA contingent consideration to fair value (\$5.2 million), costs relating to the One Shire reorganization, including costs relating to the relocation of staff from Chesterbrook to Lexington (\$15.2 million), tax effect of adjustments, and loss from discontinued operations, net of tax (\$2.5 million);
- Legal and litigation costs: Costs related to litigation, government investigations, other disputes and external legal costs (\$0.8 million), and tax effect of adjustments;
- Other: Costs associated with AbbVie's terminated offer for Shire (\$22.0 million), interest income received in respect of cash deposited with the Canadian revenue authorities (\$1.1 million), and tax effect of adjustments; and
- Depreciation reclassification: Depreciation of \$32.3 million included in Cost of product sales, R&D and SG&A for US GAAP separately disclosed for the presentation of Non GAAP earnings.



Non GAAP reconciliation for the three months ended March 31, 2016 and 2015

The following table reconciles US GAAP net income to Non GAAP EBITDA:

	3 months ended March 31,	
	2016	2015
	\$M	\$M
US GAAP Net Income	419.0	410.4
Add back/(deduct):		
(Gain)/loss from discontinued operations, net of tax	(9.5)	2.5
Equity in losses of equity method investees, net of taxes	0.1	1.0
Income taxes	82.1	57.4
Other expense/ (income), net	8.5	(4.3)
Interest expense	44.7	9.6
Interest income	(1.0)	(2.0)
US GAAP Operating income from continuing operations	543.9	474.6
Amortization	134.6	88.3
Depreciation	34.3	32.3
Acquisition and integration activities	103.9	86.9
Divestments, reorganizations and discontinued operations	(0.9)	10.0
Legal and litigation costs	15.0	0.8
Other	-	22.0
Non GAAP EBITDA	830.8	714.9
Depreciation	(34.3)	(32.3)
Non GAAP Operating income from continuing operations	796.5	682.6
Net income margin⁽¹⁾	25%	28%
Non GAAP EBITDA margin⁽²⁾	46%	46%

(1) Net income as a percentage of total revenues.

(2) Non GAAP EBITDA as a percentage of product sales, excluding royalties and other revenues.

Non GAAP reconciliation for the three months ended March 31, 2016 and 2015

The following table reconciles US GAAP product sales to Non GAAP Gross Margin:

US GAAP Product Sales

(Deduct) / add back:

Cost of product sales (US GAAP)

Unwind of inventory fair value step-up

Costs of employee retention awards following AbbVie's terminated offer

Depreciation

Non GAAP Gross Margin

Non GAAP Gross Margin % ⁽¹⁾

(1) Gross Product Margin as a percentage of product sales

3 months ended March 31,	
2016	2015
\$M	\$M
1,627.3	1,423.2
(248.6)	(227.8)
12.8	11.2
-	2.7
8.3	11.7
1,399.8	1,221.0
86.0%	85.8%

The following table reconciles US GAAP interest expense to Non GAAP interest expense:

US GAAP interest expense

Amortization of one-time upfront borrowing costs for Baxalta and Dyax

Non GAAP interest expense

3 months ended March 31,	
2016	2015
\$M	\$M
44.7	9.6
(18.2)	-
26.5	9.6

The following table reconciles US GAAP net cash provided by operating activities to Non GAAP cash generation:

Net cash provided by operating activities

Tax and interest payments/(receipts), net

Non GAAP cash generation

3 months ended March 31,	
2016	2015
\$M	\$M
389.5	561.6
102.8	(45.8)
492.3	515.8

The following table reconciles US GAAP net cash provided by operating activities to Non GAAP free cash flow:

Net cash provided by operating activities

Capital expenditures

Non GAAP free cash flow

3 months ended March 31,	
2016	2015
\$M	\$M
389.5	561.6
(51.6)	(19.8)
337.9	541.8

Non GAAP net debt comprises:

Cash and cash equivalents

Long term borrowings

Short term borrowings

Other debt

Non GAAP net debt

March 31,	December 31,
2016	2015
\$M	\$M
69.0	135.5
(4,654.0)	(69.9)
(2,211.3)	(1,511.5)
(12.7)	(13.4)
(6,809.0)	(1,459.3)

NOTES TO EDITORS

Shire enables people with life-altering conditions to lead better lives.

Our strategy is to focus on developing and marketing innovative specialty medicines to meet significant unmet patient needs.

We focus on providing treatments in Rare Diseases, Neuroscience, Gastrointestinal and Internal Medicine and we are developing treatments for symptomatic conditions treated by specialist physicians in other targeted therapeutic areas, such as Ophthalmics.

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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 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. or 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.



NON GAAP MEASURES

This press release contains financial measures not prepared in accordance with US GAAP. These measures are referred to as “Non GAAP” measures and include: *Non GAAP operating income*; *Non GAAP net income*; *Non GAAP diluted earnings per ADS*; *effective tax rate on Non GAAP income before income taxes and earnings/(losses) of equity method investees (“effective tax rate on Non GAAP income”)*; *Non GAAP cost of product sales*; *Non GAAP gross margin*; *Non GAAP R&D*; *Non GAAP SG&A*; *Non GAAP other income/(expense)*; *Non GAAP interest income*; *Non GAAP interest expense*; *Non GAAP cash generation*; *Non GAAP free cash flow*, *Non GAAP net debt*, *Non GAAP EBITDA* and *Non GAAP EBITDA margin* (excluding royalties and other revenues)⁽¹⁾. These Non GAAP measures exclude the effect of certain cash and non-cash items that Shire's management believes are not related to the core performance of Shire's business.

These Non GAAP financial measures are used by Shire's management to make operating decisions because they facilitate internal comparisons of Shire's performance to historical results and to competitors' results. Shire's Remuneration Committee uses certain key Non GAAP measures when assessing the performance and compensation of employees, including Shire's executive directors.

The Non GAAP measures are presented in this press release as Shire's management believe that they will provide investors with a means of evaluating, and an understanding of how Shire's management evaluates, Shire's performance and results on a comparable basis that is not otherwise apparent on a US GAAP basis, since many non-recurring, infrequent or non-cash items that Shire's management believe are not indicative of the core performance of the business may not be excluded when preparing financial measures under US GAAP.

These Non GAAP measures should not be considered in isolation from, as substitutes for, or superior to financial measures prepared in accordance with US GAAP.

Where applicable the following items, including their tax effect, have been excluded when calculating Non GAAP earnings for both 2016 and 2015, and from our Outlook:

Amortization and asset impairments:

- Intangible asset amortization and impairment charges; and
- Other than temporary impairment of investments.

Acquisitions and integration activities:

- Up-front payments and milestones in respect of in-licensed and acquired products;
- Costs associated with acquisitions, including transaction costs, fair value adjustments on contingent consideration and acquired inventory;
- Costs associated with the integration of companies; and
- Noncontrolling interests in consolidated variable interest entities.

Divestments, reorganizations and discontinued operations:

- Gains and losses on the sale of non-core assets;
- Costs associated with restructuring and reorganization activities;
- Termination costs; and
- Income/(losses) from discontinued operations.

Legal and litigation costs:

- Net legal costs related to the settlement of litigation, government investigations and other disputes (excluding internal legal team costs).

Other:

- Net income tax credit (being income tax, interest and estimated penalties) related to the settlement of certain tax positions with the Canadian revenue authorities; and
- Costs associated with AbbVie's terminated offer for Shire, including costs of employee retention awards.

Depreciation, which is included in Cost of product sales, R&D and SG&A costs in our US GAAP results, has been separately disclosed for the presentation of 2016 and 2015 Non GAAP earnings.

⁽¹⁾ Non GAAP EBITDA (as calculated on page 21 of this announcement) as a percentage of product sales, excluding royalties and other revenues.

Cash generation represents net cash provided by operating activities, excluding up-front and milestone payments for in-licensed and acquired products, tax and interest payments.

Free cash flow represents net cash provided by operating activities, excluding up-front and milestone payments for in-licensed and acquired products, but including capital expenditure in the ordinary course of business.

Non GAAP net debt represents US GAAP cash and cash equivalents less US GAAP short and long term borrowings and other debt.

A reconciliation of Non GAAP financial measures to the most directly comparable measure under US GAAP is presented on pages 19 to 22.

Growth at CER, which is a Non GAAP measure, is computed by restating 2016 results using average 2015 foreign exchange rates for the relevant period.

Average exchange rates used by Shire for Q1 2016 were \$1.43:£1.00 and \$1.09:€1.00 (2015: \$1.54:£1.00 and \$1.15:€1.00).

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