

Shire delivers strong Q1 2017 revenue growth while advancing late-stage pipeline

Commercial execution, efficiency improvements, and debt pay-down remain top priorities

May 2, 2017 – Shire plc (Shire) (LSE: SHP, NASDAQ: SHPG) announces unaudited results for the three months ended March 31, 2017.

Flemming Ornskov, M.D., M.P.H., Shire Chief Executive Officer, commented:

"In the first quarter we delivered strong top-line growth with quarterly product sales of \$3.4 billion. I am especially pleased to see that our sales growth came from across our broad portfolio, with genetic diseases growing 14%, our recently launched XIIDRA product achieving a 22% market share and the Baxalta business growing at 8% on a pro forma basis. We also improved our operational efficiency, and are ahead of plan on integrating Baxalta.

"Our priorities for the rest of 2017 remain unchanged: launching new products while driving commercial excellence, generating operational efficiencies, and advancing our pipeline of novel therapies. Additionally, we continue to prioritize paying down debt, and we are on track to achieve our full-year financial guidance.

"Looking ahead, I see tremendous opportunity for further growth as we continue to build on our position as the global leader in treating patients with rare diseases."

Financial Highlights	Q1 2017 ⁽¹⁾	Growth ⁽¹⁾	Non GAAP CER ⁽¹⁾⁽²⁾
Product sales	\$3,412 million	+110%	+110%
Product sales excluding legacy Baxalta	\$1,807 million	+11%	+11%
Total revenues	\$3,572 million	+109%	+110%
Operating income from continuing operations	\$497 million	(9%)	
Non GAAP operating income ⁽²⁾	\$1,454 million	+82%	+82%
Net income margin ⁽³⁾⁽⁴⁾	10%	(15ppc)	
Non GAAP EBITDA margin ⁽²⁾⁽⁴⁾	44%	(5ppc)	
Net income	\$375 million	(11%)	
Non GAAP net income ⁽²⁾	\$1,102 million	+74%	
Diluted earnings per ADS ⁽⁵⁾	\$1.23	(42%)	
Non GAAP diluted earnings per ADS ⁽²⁾⁽⁵⁾	\$3.63	+14%	+14%
Net cash provided by operating activities	\$459 million	+18%	
Non GAAP free cash flow ⁽²⁾	\$247 million	(27%)	

⁽¹⁾ Results include Baxalta Inc. (Baxalta) (acquired on June 3, 2016) and Dyax Corp. (Dyax) (acquired on January 22, 2016), unless otherwise noted. Percentages compare to equivalent 2016 period. ⁽²⁾ 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 – 21. ⁽³⁾ US GAAP net income as a percentage of total revenues. ⁽⁴⁾ Percentage point change (ppc). ⁽⁵⁾ Diluted weighted average number of ordinary shares 911.8 million.

Financial Highlights

- Delivered product sales growth of 110% with strong legacy Shire sales and the inclusion of legacy Baxalta sales.
- Achieved combined pro forma sales growth of 9%; legacy Shire sales growth of 11% and legacy Baxalta pro forma sales growth of 8%.
- Generated Non GAAP earnings per ADS of \$3.63, reflecting strong business fundamentals and operational discipline.
- Ahead of schedule with Baxalta integration and on-track to achieve at least \$700 million in synergies by year 3.
- Debt pay-down continued during the quarter and we remain on-track to achieve our year end debt target.

Product and Pipeline Highlights

- Continued to drive expansion of the U.S. dry eye disease market, with XIIDRA increasing its market share to 22% as of March 2017.
- Increased CINRYZE sales by 38% to \$226 million, reflecting higher patient demand and improvements in available supply.
- Increasing demand for our Immunology products, with pro forma sales growth for immunoglobulin therapies and bio therapeutics of 10% and 19% respectively.
- Expect U.S. Food and Drug Administration (FDA) decision for SHP465 in Attention Deficit Hyperactivity Disorder (ADHD) on or before June 20, 2017.
- Completed enrollment in SHP643 open-label extension study; topline pivotal study results expected in Q2 2017.
- Initiated Phase 3 trials for SHP640 and SHP620 in patients with bacterial and adenoviral conjunctivitis and cytomegalovirus infection, respectively.

FINANCIAL SUMMARY - FIRST QUARTER 2017 COMPARED TO FIRST QUARTER 2016

Revenues

- Product sales increased 110% to \$3,412 million (Q1 2016: \$1,627 million), primarily due to including \$1,605 million of legacy Baxalta sales.
- Product sales excluding legacy Baxalta increased 11% primarily due to growth from our Genetic Diseases and Internal Medicine franchises, up 14% and 9%, respectively, as well as sales from our Ophthalmology franchise of \$39 million.
- Royalties and other revenues increased 95% to \$160 million, as Q1 2017 benefited from additional revenue acquired with Baxalta, primarily related to contract manufacturing activities.

Operating results

- Operating income decreased 9% to \$497 million (Q1 2016: \$544 million), primarily due to the impact of acquisition accounting, including higher expense related to the unwind of inventory fair value adjustments and amortization of acquired intangible assets, partially offset by the inclusion of Baxalta operating income and higher revenue from legacy Shire products.
- Non GAAP operating income increased 82% to \$1,454 million (2016: \$797 million), primarily due to including Baxalta's operating income and higher revenue from legacy Shire products.
- Non GAAP EBITDA margin as a percentage of total revenues decreased to 44% (Q1 2016: 49%), primarily due to the impact of lower margin product franchises acquired with Baxalta as well as XIIDRA marketing costs.

Earnings per share (EPS)

- Diluted earnings per American Depositary Shares (ADS) decreased 42% to \$1.23 (Q1 2016: \$2.12). The decrease was primarily due to lower operating income resulting from the impact of acquisition accounting, combined with the impact of additional shares issued as consideration for the Baxalta transaction.
- Non GAAP diluted earnings per ADS increased 14% to \$3.63 (Q1 2016: \$3.19), as higher Non GAAP operating income more than offset the impact of additional shares issued as consideration for the Baxalta transaction.

Cash flows

- Net cash provided by operating activities increased 18% to \$459 million (Q1 2016: \$390 million), primarily due to strong cash receipts from higher sales, partially offset by a payment of \$346 million associated with the settlement of the DERMAGRAFT litigation.
- Non GAAP free cash flow, decreased 27% to \$247 million (Q1 2016: \$338 million), as the growth in net cash provided by operating activities noted above, was more than offset by an increase of \$161 million in capital expenditures, primarily related to our continued investment in manufacturing operations.

Debt

- Non GAAP net debt at March 31, 2017 decreased \$263 million since December 31, 2016, to \$22,176 million (December 31, 2016: \$22,439 million). The decrease was primarily due to a \$423 million net repayment of debt being partially offset by a lower cash balance. Non GAAP net debt represents aggregate long and short term borrowings of \$22,193 million, and other debt, primarily capital leases, of \$352 million, partially offset by cash and cash equivalents of \$369 million.

OUTLOOK

We are reiterating our full year 2017 guidance and are expecting another strong year for Shire, building on our excellent financial performance in 2016.

In addition to the guidance in the table below, we expect depreciation expense to be \$400 - \$450 million and capital expenditure to be approximately \$1 billion in 2017 reflecting our larger footprint and important investments to support our growth aspirations.

The Non GAAP diluted earnings per ADS forecast assumes a weighted average number of 914 million fully diluted ordinary shares outstanding for 2017.

Our US GAAP diluted earnings per ADS outlook reflects anticipated amortization, integration and reorganization costs.

Full Year 2017	US GAAP Outlook	Non GAAP Outlook⁽¹⁾
Total product sales	\$14.5 - \$14.8 billion	\$14.5 - \$14.8 billion
Royalties & other revenues	\$600 - \$700 million	\$600 - \$700 million
Gross margin as a percentage of total revenue ⁽²⁾	67.0% - 69.0%	74.5% - 76.5%
Combined R&D and SG&A	\$5.2 - \$5.5 billion	\$5.0 - \$5.3 billion
Net interest/other	\$500 - \$600 million	\$500 - \$600 million
Effective tax rate	~11%	16% - 17%
Diluted earnings per ADS ⁽³⁾	\$6.95 - \$7.55	\$14.60 - \$15.20

⁽¹⁾ For a list of items excluded from Non GAAP Outlook, refer to pages 25 - 26 of this release.

⁽²⁾ Gross margin as a percentage of total revenues excludes amortization of acquired intangible assets.

⁽³⁾ See page 21 for a reconciliation between US GAAP diluted earnings per ADS and Non GAAP diluted earnings per ADS.

RECENT DEVELOPMENTS

Business Development

Shire to License P-321

- On May 1, 2017, Shire announced it agreed to license the exclusive worldwide rights to P-321 from Parion Sciences. P-321 is a Phase 2 investigational epithelial sodium channel inhibitor for the potential treatment of dry eye disease in adults. Shire will develop, and if approved, commercialize this compound which would expand our leadership position in ophthalmics and provide another important treatment option for patients with dry eye disease.

Products

NATPAR for the treatment of chronic hypoparathyroidism

- On April 26, 2017, Shire announced the European Commission (EC) granted Conditional Marketing Authorization for NATPAR (rhPTH[1-84]), the first recombinant human protein with the full length 84-amino-acid sequence of endogenous parathyroid hormone (PTH), as an adjunctive treatment for adult patients with chronic hypoparathyroidism who cannot be adequately controlled with standard therapy alone.

VYVANSE for the treatment of ADHD and Binge Eating Disorder (BED)

- On April 18, 2017, Shire announced that VYVANSE (lisdexamfetamine dimesylate) CII is now available in the United States in a new chewable tablet formulation, following FDA approval in January 2017.

INTUNIV for the treatment of ADHD in Japan

- On March 30, 2017, Shire's partner in Japan, Shionogi & Co., Ltd, received approval from the Japanese Ministry of Health, Labor and Welfare to manufacture and market INTUNIV for ADHD in Japan.

CINRYZE for the treatment of Hereditary Angioedema (HAE)

- On March 16, 2017, the EC approved a label extension for CINRYZE (C1 inhibitor [human]), broadening its use to children with HAE. CINRYZE is now the first and only treatment indicated for routine prevention of angioedema attacks in children aged six years or older who have severe and recurrent attacks of HAE and cannot tolerate or are not adequately protected by oral preventative treatments, or who are inadequately managed with repeated acute treatment. CINRYZE is also now approved for acute treatment and pre-procedure prevention of angioedema attacks in children aged two years or older with HAE.

Pipeline

SHP655 for the treatment of congenital thrombotic thrombocytopenic purpura (cTTP)

- On March 22, 2017, the FDA granted Fast Track Designation for recombinant ADAMTS13 (SHP655) for the treatment of acute episodes of cTTP in patients with a congenital deficiency of the von Willebrand factor-cleaving protease ADAMTS13.

SHP643 for the treatment of HAE

- The SHP643 open-label extension study completed enrollment in March 2017. Topline pivotal Phase 3 study results are expected in Q2 2017.

SHP640 for the treatment of bacterial and adenoviral conjunctivitis

- The global Phase 3 clinical development program will have clinical sites in over 20 countries. Patient recruitment has started and the first patient visit occurred in March 2017. The topline data is expected in Q2 2018.

SHP639 for the treatment of Glaucoma

- In March 2017, Shire submitted an Investigational New Drug (IND) application for SHP639. The IND is for the initiation of first in human clinical studies of SHP639 for the reduction of elevated intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension.

ADDITIONAL INFORMATION

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Dial in details for the **live conference call** for investors at 14:00 GMT / 9:00 EDT on May 2, 2017:

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:	74545877#
Live Webcast:	Click here

The quarterly earnings presentation will be available today at 13:00 BST / 8:00 EDT on:

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

OVERVIEW OF FIRST QUARTER 2017 FINANCIAL RESULTS COMPARED TO FIRST QUARTER 2016

1. Product Sales

Product sales increased 110% to \$3,412 million (Q1 2016: \$1,627 million), primarily due to including legacy Baxalta sales since June 2016. Excluding legacy Baxalta, product sales increased 11%.

(in millions)				Total Sales Year on year growth	
	U.S. Sales	International Sales	Total Sales	Reported	Non GAAP CER
Product sales by franchise					
HEMOPHILIA	\$ 341.5	\$ 308.9	\$ 650.4	N/A	N/A
INHIBITOR THERAPIES	70.7	149.8	220.5	N/A	N/A
Hematology total	412.2	458.7	870.9	N/A	N/A
CINRYZE	216.4	9.5	225.9	+38%	+38%
ELAPRASE	38.2	102.4	140.6	+14%	+14%
FIRAZYR	111.6	16.9	128.5	+0%	+0%
REPLAGAL	—	109.7	109.7	+6%	+8%
VPRIV	35.5	44.3	79.8	-5%	-3%
KALBITOR	11.7	—	11.7	+13%	+13%
Genetic Diseases total	413.4	282.8	696.2	+14%	+14%
IMMUNOGLOBULIN THERAPIES	405.4	92.9	498.3	N/A	N/A
BIO THERAPEUTICS	69.7	108.2	177.9	N/A	N/A
Immunology total	475.1	201.1	676.2	N/A	N/A
VYVANSE	508.5	55.2	563.7	+11%	+10%
ADDERALL XR	59.3	5.6	64.9	-34%	-35%
Other Neuroscience	1.6	23.1	24.7	+12%	+15%
Neuroscience total	569.4	83.9	653.3	+4%	+4%
LIALDA/MEZAVANT	153.1	22.0	175.1	+4%	+4%
PENTASA	69.1	—	69.1	+8%	+8%
GATTEX/REVESTIVE	57.0	12.0	69.0	+33%	+34%
NATPARA	29.6	0.1	29.7	+90%	+90%
Other Internal Medicine	25.0	50.9	75.9	-10%	-9%
Internal Medicine total	333.8	85.0	418.8	+9%	+9%
Oncology total	42.3	16.0	58.3	N/A	N/A
Ophthalmology total	38.6	—	38.6	N/A	N/A
Total product sales	\$ 2,284.8	\$ 1,127.5	\$ 3,412.3	+110%	+110%

Hematology

Hematology, acquired with Baxalta in June 2016, reported product sales of \$871 million. Hematology includes sales of recombinant and plasma-derived hemophilia products (primarily factor VIII and factor IX) and inhibitor therapies. Pro forma Q1 2017 growth in Hematology was approximately 4%, with strong inhibitor therapies growth of 12%. Q1 2017 results for both the hemophilia and inhibitor therapies benefited from the timing of large orders in our international markets.

Genetic Diseases

Genetic Diseases product sales increased 14% with growth primarily driven by CINRYZE and, to a lesser extent, ELAPRASE.

CINRYZE sales increased by 38% due to an increase in the number of patients on therapy and the impact of U.S. stocking following supply improvements. ELAPRASE sales increased by 14% due to an increase in the number of patients on therapy and the timing of large orders in our international markets.

Immunology

Immunology, acquired with Baxalta in June 2016, reported product sales of \$676 million. Immunology includes sales of antibody-replacement immunoglobulin and bio therapeutics therapies. Pro forma Q1 2017 growth in Immunology was approximately 12% as the franchise benefited from increased demand and the timing of large orders in our international markets.

Neuroscience

Neuroscience product sales increased 4% with growth primarily driven by VYVANSE.

VYVANSE sales increased 11% due to year-over-year prescription growth in the U.S., the benefit of a price increase taken since Q1 2016 and growth in our international markets.

ADDERALL XR sales decreased 34% primarily due to the impact of additional generic competition since August 2016 and destocking in Q1 2017 compared with stocking in Q1 2016.

Internal Medicine

Internal Medicine product sales increased 9%, with strong growth from GATTEX/REVESTIVE and NATPARA.

GATTEX/REVESTIVE and NATPARA continued to perform well with sales increasing 33% and 90%, respectively, primarily due to an increase in the numbers of patients on therapy.

Oncology

Oncology, acquired with Baxalta in June 2016, reported sales of \$58 million. Oncology includes sales of ONCASPAR and ONIVYDE, the latter of which was approved in the EU on October 18, 2016.

Ophthalmology

Ophthalmology product sales relate to XIIDRA, which was made available to patients on August 29, 2016. XIIDRA contributed \$39 million of product sales, and achieved a U.S. market share of 22% as of March 2017.

Baxalta pro forma product sales growth

The following table presents Q1 2017 reported legacy Baxalta product sales compared with recast Q1 2016 pro forma sales as previously reported by Baxalta following the separation from Baxter.

(in millions)				Pro forma	
	U.S. Sales	International Sales	Total Sales	Year on year growth Reported	Non GAAP CER
Product sales by franchise					
HEMOPHILIA	\$ 341.5	\$ 308.9	\$ 650.4	+1%	+1%
INHIBITOR THERAPIES	70.7	149.8	220.5	+12%	+14%
Hematology total	412.2	458.7	870.9	+4%	+4%
IMMUNOGLOBULIN THERAPIES	405.4	92.9	498.3	+10%	+11%
BIO THERAPEUTICS	69.7	108.2	177.9	+19%	+21%
Immunology total	475.1	201.1	676.2	+12%	+13%
Oncology total	42.3	16.0	58.3	+13%	+13%
Total	\$ 929.6	\$ 675.8	\$ 1,605.4	+8%	+8%

2. Royalties and other revenues

(in millions)	Revenue	Year on year growth	
		Reported	Non GAAP CER
SENSIPAR Royalties	\$ 38.9	+3%	+3%
3TC and ZEFFIX Royalties	14.5	-3%	-3%
ADDERALL XR Royalties	12.5	+116%	+116%
FOSRENOL Royalties	8.6	-7%	-9%
Other Royalties and Revenues	85.5	+506%	+513%
Total Royalties and Other Revenues	\$ 160.0	+95%	+96%

Royalties and Other Revenues increased 95%, primarily due to including \$46 million of contract manufacturing revenue acquired with Baxalta.

3. Financial Details

Cost of sales

(in millions)	Q1 2017	% of total revenues	Q1 2016	% of total revenues
	Cost of sales (US GAAP)	\$ 1,327.0	37%	\$ 248.6
Expense related to the unwind of inventory fair value adjustments	(480.4)		(12.8)	
Depreciation	(72.1)		(8.3)	
Non GAAP cost sales	\$ 774.5	22%	\$ 227.5	13%

Cost of sales as a percentage of total revenues increased to 37% primarily due to the impact of higher expense related to the unwind of inventory fair value adjustments and depreciation following the acquisitions of Baxalta and Dyax and, to a lesser extent, the impact of lower margin product franchises acquired with Baxalta.

Non GAAP cost of sales as a percentage of total revenues increased to 22%, primarily due to the impact of lower margin product franchises acquired with Baxalta.

R&D

(in millions)	Q1 2017	% of total revenues	Q1 2016	% of total revenues
	R&D (US GAAP)	\$ 379.3	11%	\$ 217.1
Depreciation	(13.4)		(5.9)	
Non GAAP R&D	\$ 365.9	10%	\$ 211.2	12%

R&D increased by \$162 million, or 75%, primarily due to the inclusion of Baxalta costs.

Non GAAP R&D increased by \$155 million, or 73%, primarily due to the inclusion of Baxalta costs. Non GAAP R&D expense as a percentage of total revenues decreased 2 percentage points.

SG&A

(in millions)	Q1 2017	% of total revenues	Q1 2016	% of total revenues
SG&A (US GAAP) ⁽¹⁾	\$ 888.9	25%	\$ 474.9	28%
Legal and litigation costs	—		(15.0)	
One-time employee related costs	4.0		—	
Depreciation	(37.4)		(20.1)	
Non GAAP SG&A	\$ 855.5	24%	\$ 439.8	26%

⁽¹⁾ Reported SG&A for 2016 has been recast to exclude amortization of acquired intangible assets, which is now presented as a separate line item in the Unaudited Consolidated Statements of Operations.

SG&A increased by \$414 million, or 87%, primarily due to the inclusion of Baxalta related costs and XIIDRA marketing costs.

Non GAAP SG&A increased by \$416 million, or 95%. Non GAAP SG&A as a percentage of total revenues decreased 2 percentage points.

Amortization of acquired intangible assets

Shire recorded amortization of acquired intangible assets of \$364 million (Q1 2016: \$135 million). The increase is primarily related to amortization on the intangible assets acquired with the Baxalta transaction.

Integration and acquisition costs

In Q1 2017, Shire recorded integration and acquisition costs of \$116 million, primarily related to the integration of Baxalta. These costs include employee severance and acceleration of stock compensation, third-party professional fees and expenses associated with facility consolidations.

In Q1 2016, Shire recorded integration and acquisition costs of \$91 million, primarily related to the integration and acquisition of Dyax, and costs associated with the proposed acquisition of Baxalta. These costs include legal, investment banking and other transaction-related fees, as well as integration costs related to employee severance and acceleration of stock compensation, and third-party professional fees.

Other expense, net

(in millions)	Q1 2017	Q1 2016
Other expense, net (US GAAP)	\$ (134.7)	\$ (52.2)
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	1.8	18.2
Loss on sale of long term investments	—	6.0
Non GAAP Other expense, net	\$ (132.9)	\$ (28.0)

Other expense, net increased by \$83 million, primarily due to higher interest expense incurred on borrowings used to fund the acquisitions of Dyax and Baxalta.

Non GAAP Other expense, net increased by \$105 million, primarily due to higher interest expense as noted above.

Taxation

(in millions)	Q1 2017	Effective tax rate	Q1 2016	Effective tax rate
Income tax expense (US GAAP)	\$ 6.8	2%	\$ 82.1	17%
Tax effect of adjustments	210.9		54.5	
Non GAAP Income tax expense	\$ 217.7	16%	\$ 136.6	18%

The effective tax rate on US GAAP income in Q1 2017 was 2% (Q1 2016: 17%) and on a Non GAAP basis was 16% (Q1 2016: 18%).

The effective tax rate in Q1 2017 on US GAAP income from continuing operations is low primarily due to the combined impact of the relative quantum of the profit before tax for the period by jurisdiction with significant integration costs incurred in higher tax territories. Additionally, discrete events in Q1 2017, including the tax benefit from employee exercises of stock compensation, which is now required to be recorded as a discrete item in the quarter in which it occurs, contributed to the low rate.

The Q1 2017 Non GAAP rate is lower than the same period in 2016, primarily due to changes in the mix of jurisdictional profitability related to the Baxalta acquisition.

Discontinued operations

The gain from discontinued operations in Q1 2017 was \$20 million, net of taxes of \$12 million, primarily due to the return of funds previously held in escrow related to the acquisition of the DERMAGRAFT business. The gain in Q1 2016 was \$10 million, net of taxes of \$5 million, primarily related to the reimbursement of legal costs associated with the divested DERMAGRAFT business.

FINANCIAL INFORMATION

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Unaudited US GAAP Consolidated Balance Sheets

(in millions, except par value of shares)

	March 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 369.0	\$ 528.8
Restricted cash	34.1	25.6
Accounts receivable, net	2,579.5	2,616.5
Inventories	3,345.8	3,562.3
Prepaid expenses and other current assets	787.2	806.3
Total current assets	<u>7,115.6</u>	<u>7,539.5</u>
Non-current assets:		
Investments	226.2	191.6
Property, plant and equipment (PP&E), net	6,496.1	6,469.6
Goodwill	19,149.1	17,888.2
Intangible assets, net	32,834.1	34,697.5
Deferred tax asset	125.5	96.7
Other non-current assets	213.5	152.3
Total assets	<u>\$ 66,160.1</u>	<u>\$ 67,035.4</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,551.3	\$ 4,312.4
Short term borrowings and capital leases	3,049.5	3,068.0
Other current liabilities	409.6	362.9
Total current liabilities	<u>7,010.4</u>	<u>7,743.3</u>
Non-current liabilities:		
Long term borrowings and capital leases	19,495.9	19,899.8
Deferred tax liability	7,752.6	8,322.7
Other non-current liabilities	2,169.3	2,121.6
Total liabilities	<u>36,428.2</u>	<u>38,087.4</u>
Equity:		
Common stock of 5p par value; 1,500 shares authorized; and 914.1 shares issued and outstanding (2016: 1,500 shares authorized; and 912.2 shares issued and outstanding)	81.4	81.3
Additional paid-in capital	24,850.9	24,740.9
Treasury stock: 8.4 shares (2016: 9.1 shares)	(283.0)	(301.9)
Accumulated other comprehensive loss	(1,227.1)	(1,497.6)
Retained earnings	6,309.7	5,925.3
Total equity	<u>29,731.9</u>	<u>28,948.0</u>
Total liabilities and equity	<u>\$ 66,160.1</u>	<u>\$ 67,035.4</u>

Unaudited US GAAP Consolidated Statements of Operations
(in millions)

	3 months ended March 31,	
	2017	2016
Revenues:		
Product sales	\$ 3,412.3	\$ 1,627.3
Royalties & other revenues	160.0	82.0
Total revenues	3,572.3	1,709.3
Costs and expenses:		
Cost of sales	1,327.0	248.6
Research and development	379.3	217.1
Selling, general and administrative ⁽¹⁾	888.9	474.9
Amortization of acquired intangible assets	364.0	134.6
Integration and acquisition costs	116.0	91.1
Reorganization costs	5.5	3.3
Gain on sale of product rights	(5.5)	(4.2)
Total operating expenses	3,075.2	1,165.4
Operating income from continuing operations	497.1	543.9
Interest income	3.1	1.0
Interest expense	(142.3)	(44.7)
Other income/(expense), net	4.5	(8.5)
Total other expense, net	(134.7)	(52.2)
Income from continuing operations before income taxes and equity in losses of equity method investees	362.4	491.7
Income taxes	(6.8)	(82.1)
Equity in losses of equity method investees, net of taxes	(0.8)	(0.1)
Income from continuing operations, net of taxes	354.8	409.5
Gain from discontinued operations, net of taxes	20.2	9.5
Net income	\$ 375.0	\$ 419.0

⁽¹⁾ Reported SG&A for 2016 has been recast to exclude amortization of acquired intangible assets, which is now presented as a separate line item.

Unaudited US GAAP Consolidated Statements of Operations (continued)*(in millions, except per share amounts)*

	3 months ended March 31,	
	2017	2016
Earnings per Ordinary Share – basic		
Earnings from continuing operations	\$ 0.39	\$ 0.69
Earnings from discontinued operations	0.02	0.02
Earnings per Ordinary Share – basic	<u>\$ 0.41</u>	<u>\$ 0.71</u>
Earnings per ADS – basic	<u>\$ 1.24</u>	<u>\$ 2.12</u>
Earnings per Ordinary Share – diluted		
Earnings from continuing operations	\$ 0.39	\$ 0.69
Earnings from discontinued operations	0.02	0.02
Earnings per Ordinary Share – diluted	<u>\$ 0.41</u>	<u>\$ 0.71</u>
Earnings per ADS – diluted	<u>\$ 1.23</u>	<u>\$ 2.12</u>
Weighted average number of shares:		
Basic	<u>904.1</u>	591.7
Diluted	<u>911.8</u>	593.3

Unaudited US GAAP Consolidated Statements of Cash Flows
(in millions)

	3 months ended March 31,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 375.0	\$ 419.0
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	486.9	168.9
Share based compensation	52.7	18.3
Amortization of deferred financing fees	3.2	20.0
Expense related to the unwind of inventory fair value adjustments	480.4	12.8
Change in deferred taxes	(135.5)	(10.1)
Change in fair value of contingent consideration	(3.5)	11.4
Other, net	26.8	(14.5)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(35.3)	(100.9)
Increase in sales deduction accrual	17.5	73.6
Increase in inventory	(151.8)	(32.2)
Decrease/(increase) in prepayments and other assets	14.2	(22.2)
Decrease in accounts payable and other liabilities	(671.5)	(154.6)
Net cash provided by operating activities	459.1	389.5
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of PP&E and non-current investments	(212.5)	(51.6)
Purchases of businesses, net of cash acquired	—	(5,692.8)
Movements in restricted cash	(8.5)	64.8
Other, net	1.2	5.5
Net cash used in investing activities	(219.8)	(5,674.1)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from revolving line of credit, long term and short term borrowings	1,401.9	6,305.0
Repayment of revolving line of credit, long term and short term borrowings	(1,825.7)	(995.1)
Debt issuance costs	—	(93.8)
Proceeds from exercise of options	22.1	0.1
Other, net	(0.1)	0.9
Net cash (used in)/provided by financing activities	(401.8)	5,217.1
Effect of foreign exchange rate changes on cash and cash equivalents	2.7	1.0
Net decrease in cash and cash equivalents	(159.8)	(66.5)
Cash and cash equivalents at beginning of period	528.8	135.5
Cash and cash equivalents at end of period	\$ 369.0	\$ 69.0

Selected Notes to the Unaudited US GAAP Financial Statements

(1) Earnings Per Share (EPS)

(in millions)

	3 months ended March 31,	
	2017	2016
Income from continuing operations	\$ 354.8	\$ 409.5
Gain from discontinued operations	20.2	9.5
Numerator for EPS	<u>\$ 375.0</u>	<u>\$ 419.0</u>
Weighted average number of shares:		
Basic	904.1	591.7
Effect of dilutive shares:		
Share based awards to employees	7.7	1.6
Diluted	<u>911.8</u>	<u>593.3</u>

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

Share based awards to employees	<u>7.3</u>	<u>4.0</u>
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Selected Notes to the Unaudited US GAAP Financial Statements

(2) Analysis of revenues

(in millions)

	3 months ended March 31,	
	2017	2016
Product sales by franchise		
HEMOPHILIA	\$ 650.4	\$ —
INHIBITOR THERAPIES	220.5	—
Hematology	870.9	—
CINRYZE	225.9	164.2
ELAPRASE	140.6	123.6
FIRAZYR	128.5	128.3
REPLAGAL	109.7	103.2
VPRIV	79.8	83.6
KALBITOR	11.7	10.4
Genetic Diseases	696.2	613.3
IMMUNOGLOBULIN THERAPIES	498.3	—
BIO THERAPEUTICS	177.9	—
Immunology	676.2	—
VYVANSE	563.7	509.2
ADDERALL XR	64.9	98.8
Other Neuroscience	24.7	22.1
Neuroscience	653.3	630.1
LIALDA/MEZAVANT	175.1	168.0
PENTASA	69.1	64.0
GATTEX/REVESTIVE	69.0	51.7
NATPARA	29.7	15.6
Other Internal Medicine	75.9	84.6
Internal Medicine	418.8	383.9
Oncology	58.3	—
Ophthalmology	38.6	—
Total product sales	3,412.3	1,627.3
Royalties and Other Revenues:		
SENSIPAR Royalties	38.9	37.9
3TC and ZEFFIX Royalties	14.5	15.0
ADDERALL XR Royalties	12.5	5.8
FOSRENOL Royalties	8.6	9.2
Other Royalties and Revenues	85.5	14.1
Total Royalties and Other Revenues	160.0	82.0
Total Revenues	\$ 3,572.3	\$ 1,709.3

Non GAAP reconciliations

(in millions)

Reconciliation of US GAAP net income to Non GAAP EBITDA and Non GAAP Operating income:

	3 months ended March 31,	
	2017	2016
US GAAP Net income	\$ 375.0	\$ 419.0
Add back/(deduct):		
Gain from discontinued operations, net of taxes	(20.2)	(9.5)
Equity in losses of equity method investees, net of taxes	0.8	0.1
Income taxes	6.8	82.1
Other expense, net	134.7	52.2
US GAAP Operating income from continuing operations	497.1	543.9
Add back/(deduct) Non GAAP adjustments:		
Expense related to the unwind of inventory fair value adjustments	480.4	12.8
Legal and litigation costs	—	15.0
Amortization of acquired intangible assets	364.0	134.6
Integration and acquisition costs	116.0	91.1
Reorganization costs	5.5	3.3
Gain on sale of product rights	(5.5)	(4.2)
Depreciation	122.9	34.3
Other Non GAAP adjustments	(4.0)	—
Non GAAP EBITDA	1,576.4	830.8
Depreciation	(122.9)	(34.3)
Non GAAP Operating income	\$ 1,453.5	\$ 796.5
Net income margin⁽¹⁾	10%	25%
Non GAAP EBITDA margin⁽²⁾	44%	49%

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

⁽²⁾ Non GAAP EBITDA as a percentage of total revenues.

Reconciliation of revenues to Non GAAP Gross Margin:

	3 months ended March 31,	
	2017	2016
Revenues	\$ 3,572.3	\$ 1,709.3
(Deduct)/add back:		
Cost of sales (US GAAP)	(1,327.0)	(248.6)
Expense related to the unwind of inventory fair value adjustments	480.4	12.8
Depreciation	72.1	8.3
Non GAAP Gross Margin	\$ 2,797.8	\$ 1,481.8
Non GAAP Gross Margin % ⁽¹⁾	78.3%	86.7%

⁽¹⁾ Non GAAP Gross Margin as a percentage of total revenues.

Non GAAP reconciliations

(in millions, except per ADS amounts)

Reconciliation of US GAAP net income to Non GAAP net income:

	3 months ended March 31,	
	2017	2016
US GAAP net income	\$ 375.0	\$ 419.0
Expense related to the unwind of inventory fair value adjustments	480.4	12.8
Legal and litigation costs	—	15.0
Amortization of acquired intangible assets	364.0	134.6
Integration and acquisition costs	116.0	91.1
Reorganization costs	5.5	3.3
Gain on sale of product rights	(5.5)	(4.2)
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	1.8	18.2
Gain from discontinued operations	(31.8)	(15.0)
Other Non GAAP adjustments	(4.0)	6.0
Tax effect of adjustments	(199.3)	(49.0)
Non GAAP net income	\$ 1,102.1	\$ 631.8

Reconciliation of US GAAP diluted earnings per ADS to Non GAAP diluted earnings per ADS:

	3 months ended March 31,	
	2017	2016
US GAAP diluted earnings per ADS	\$ 1.23	\$ 2.12
Expense related to the unwind of inventory fair value adjustments	1.58	0.06
Legal and litigation costs	—	0.08
Amortization of acquired intangible assets	1.20	0.68
Integration and acquisition costs	0.38	0.46
Reorganization costs	0.02	0.02
Gain on sale of product rights	(0.02)	(0.02)
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	0.01	0.09
Gain from discontinued operations	(0.10)	(0.08)
Other Non GAAP adjustments	(0.01)	0.03
Tax effect of adjustments	(0.66)	(0.25)
Non GAAP diluted earnings per ADS	\$ 3.63	\$ 3.19

Reconciliation of US GAAP net cash provided by operating activities to Non GAAP free cash flow:

	3 months ended March 31,	
	2017	2016
Net cash provided by operating activities	\$ 459.1	\$ 389.5
Capital expenditure	(212.5)	(51.6)
Non GAAP free cash flow	\$ 246.6	\$ 337.9

Non GAAP reconciliations

(in millions, except per ADS amounts)

Non GAAP net debt comprises:

	March 31, 2017	December 31, 2016
Cash and cash equivalents	\$ 369.0	\$ 528.8
Long term borrowings (excluding capital leases)	(19,150.6)	(19,552.6)
Short term borrowings (excluding capital leases)	(3,042.8)	(3,061.6)
Capital leases and other debt	(352.0)	(353.6)
Non GAAP net debt	\$ (22,176.4)	\$ (22,439.0)

Reconciliation of full year 2017 US GAAP diluted earnings per ADS Outlook to Non GAAP diluted earnings per ADS Outlook:

	Full Year 2017 Outlook		
	Min		Max
US GAAP diluted earnings per ADS	\$ 6.95	—	\$ 7.55
Expense related to the unwind of inventory fair value adjustments		2.16	
Amortization of acquired intangible assets		5.40	
Acquisition and integration costs		2.00	
Reorganization costs		0.06	
Legal and litigation costs		0.04	
Amortization of one-time upfront borrowing costs for Baxalta and Dyax		0.02	
Tax effect of adjustments		(2.03)	
Non GAAP diluted earnings per ADS	\$ 14.60	—	\$ 15.20

NOTES TO EDITORS

Stephen Williams, Deputy Company Secretary is responsible for arranging the release of this announcement.

Inside Information

This announcement contains inside information.

About Shire

Shire is the leading global biotechnology company focused on serving people with rare diseases. We strive to develop best-in-class products, many of which are available in more than 100 countries, across core therapeutic areas including Hematology, Immunology, Neuroscience, Ophthalmics, Lysosomal Storage Disorders, Gastrointestinal / Internal Medicine / Endocrine and Hereditary Angioedema; and a growing franchise in Oncology.

Our employees come to work every day with a shared mission: to develop and deliver breakthrough therapies for the hundreds of millions of people in the world affected by rare diseases and other high-need conditions, and who lack effective therapies to live their lives to the fullest.

www.shire.com

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:

- Shire’s products may not be a commercial success;
- increased pricing pressures and limits on patient access as a result of governmental regulations and market developments may affect Shire’s future revenues, financial condition and results of operations;
- Shire conducts its own manufacturing operations for certain of its products and is reliant on third party contract manufacturers to manufacture other products and to provide goods and services. Some of Shire’s products or ingredients are only available from a single approved source for manufacture. Any disruption to the supply chain for any of Shire’s products may result in Shire being unable to continue marketing or developing a product or may result in Shire being unable to do so on a commercially viable basis for some period of time;
- the manufacture of Shire’s products is subject to extensive oversight by various regulatory agencies. Regulatory approvals or interventions associated with changes to manufacturing sites, ingredients or manufacturing processes could lead to, among other things, significant delays, an increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- certain of Shire’s therapies involve lengthy and complex processes, which may prevent Shire from timely responding to market forces and effectively managing its production capacity;
- Shire has a portfolio of products in various stages of research and development. The successful development of these products 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 Shire’s ability to sell or market products profitably. Fluctuations in buying or distribution patterns by such customers can adversely affect Shire’s revenues, financial conditions or results of operations;
- Shire’s products and product candidates face substantial competition in the product markets in which it operates, including competition from generics;
- adverse outcomes in legal matters, tax audits and other disputes, including Shire’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;
- inability to successfully compete for highly qualified personnel from other companies and organizations;
- failure to achieve the strategic objectives, including expected operating efficiencies, cost savings, revenue enhancements, synergies or other benefits at the time anticipated or at all with respect to Shire’s acquisitions, including NPS Pharmaceuticals Inc., Dyax Corp. or Baxalta Incorporated may adversely affect Shire’s financial condition and results of operations;
- Shire’s growth strategy depends in part upon its ability to expand its product portfolio through external collaborations, which, if unsuccessful, may adversely affect the development and sale of its products;
- a slowdown of global economic growth, or economic instability of countries in which Shire does business, as well as changes in foreign currency exchange rates and interest rates, that adversely impact the availability and cost of credit and customer purchasing and payment patterns, including the collectability of customer accounts receivable;
- failure of a marketed product to work effectively or if such a product is the cause of adverse side effects could result in damage to Shire’s reputation, the withdrawal of the product and legal action against Shire;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to Shire’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;
- Shire 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 Shire’s revenues, financial condition or results of operations;
- Shire incurred substantial additional indebtedness to finance the Baxalta acquisition, which may decrease its business flexibility and increase borrowing costs; and

a further list and description of risks, uncertainties and other matters can be found in Shire's most recent Annual Report on Form 10-K and in Shire's subsequent Quarterly Reports on Form 10-Q, in each case including those risks outlined in "ITEM 1A: Risk Factors", and in subsequent reports on Form 8-K and other Securities and Exchange Commission filings, all of which are available on Shire's website.

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 update or revise forward-looking statements, whether as a result of new information, future events or otherwise.

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 (losses/earnings) of equity method investees (effective tax rate on Non GAAP income); Non GAAP CER; Non GAAP cost of sales; Non GAAP gross margin; Non GAAP R&D; Non GAAP SG&A; Non GAAP other expense; Non GAAP free cash flow, Non GAAP net debt, Non GAAP EBITDA and Non GAAP EBITDA margin.*

The Non GAAP measures exclude the impact of certain specified items that are highly variable, difficult to predict, and of a size that may substantially impact Shire’s operations. Upfront and milestone payments related to in-licensing and acquired products that have been expensed as R&D are also excluded as specified items as they are generally uncertain and often result in a different payment and expense recognition pattern than ongoing internal R&D activities. Intangible asset amortization has been excluded from certain measures to facilitate an evaluation of current and past operating performance, particularly in terms of cash returns, and is similar to how management internally assesses performance. The Non GAAP financial measures are presented in this press release as Shire’s management believes that they will provide investors with an additional analysis of Shire’s results of operations, particularly in evaluating performance from one period to another.

Shire’s management uses Non GAAP financial measures to make operating decisions as they facilitate additional internal comparisons of Shire’s performance to historical results and to competitor’s results, and provides them to investors as a supplement to Shire’s reported results to provide additional insight into Shire’s operating performance. 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 financial measures used by Shire may be calculated different from, and therefore may not be comparable to, similarly titled measures used by other companies - refer to the section “Non GAAP Financial Measure Descriptions” below for additional information. In addition, these Non GAAP financial measures should not be considered in isolation as a substitute for, or as superior to, financial measures calculated in accordance with US GAAP, and Shire’s financial results calculated in accordance with US GAAP and reconciliations to those financial statements should be carefully evaluated.

Non GAAP Financial Measure Descriptions

Where applicable the following items, including their tax effect, have been excluded when calculating Non GAAP earnings and from our Non GAAP 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).

Additionally, in any given period Shire may have significant, unusual or non-recurring gains or losses which it may exclude from its Non GAAP earnings for that period. When applicable, these items would be fully disclosed and incorporated into the required reconciliations from US GAAP to Non GAAP measures.

Depreciation, which is included in Cost of sales, R&D and SG&A costs in our US GAAP results, has been separately disclosed for presentational purposes.

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 cash and cash equivalents less short and long term borrowings, capital leases 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 21.

Non GAAP CER growth is computed by restating 2017 results using average 2016 foreign exchange rates for the relevant period.

Average exchange rates used by Shire for the three months ended March 31, 2017 were \$1.24:£1.00 and \$1.06:€1.00 (2016: \$1.43:£1.00 and \$1.09:€1.00).

TRADEMARKS

We own or have rights to trademarks, service marks or trade names that we use in connection with the operation of our business. In addition, our names, logos and website names and addresses are owned by us or licensed by us. We also own or have the rights to copyrights that protect the content of our solutions. Solely for convenience, the trademarks, service marks, trade names and copyrights referred to in this press release are listed without the ©, ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks, trade names and copyrights. In addition, this press release may include trademarks, service marks or trade names of other companies. Our use or display of other parties' trademarks, service marks, trade names or products is not intended to, and does not imply a relationship with, or endorsement or sponsorship of us by, the trademark, service mark or trade name.