

# Press Release



## **Shire reports strong earnings growth in Q3 2017; reiterates full year guidance**

*Product sales increased 7%, mainly driven by rapid growth in Immunology franchise*

*Generated \$1.1 billion operating cash flow; remain on-track to achieve our year-end debt target*

*On track to file a NDA for SHP555 in chronic constipation in Q4 2017 and a BLA for SHP643 in hereditary angioedema by late 2017 or early 2018*

*Completed manufacturing review and identified more than \$100 million in projected additional annual savings beginning in 2019 and expected to increase to \$300 million annually by 2023*

**October 27, 2017** – Shire plc (Shire) (LSE: SHP, NASDAQ: SHPG) announces unaudited results for the three months ended September 30, 2017.

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

“We delivered strong growth this quarter with product sales up 7% to \$3.5 billion despite a CINRYZE supply shortage and a LIALDA generic entry. The Immunology franchise grew by 32%, and we saw significant contributions across our broad and diverse portfolio, evidencing our continued focus on commercial execution. We delivered strong Non GAAP EPS growth of 20%, and operating cash flow more than doubled to \$1.1 billion, which enabled us to further reduce our debt.

“We experienced a product shortage of CINRYZE during the quarter due to a manufacturing interruption at a third-party manufacturer. The issue has been addressed and production of CINRYZE has resumed. Product was shipped to customers in early October. To enhance reliability of supply, we plan to start in-house production of CINRYZE by Q1 2018, subject to FDA approval, as sustainable and unconstrained CINRYZE supply is a top priority.

“We are reiterating our 2017 full year guidance, and I look forward to updating you on the Neuroscience strategic review by year end. I continue to be highly confident in the strength and durability of our business.”

## Financial Highlights

	Q3 2017 <sup>(1)</sup>	Growth <sup>(1)</sup>	Non GAAP CER <sup>(1)(2)</sup>
Product sales	\$3,534 million	+7%	+6%
Total revenues	\$3,698 million	+7%	+6%
Operating income from continuing operations	\$709 million	N/M	
Non GAAP operating income <sup>(2)</sup>	\$1,498 million	+19%	+18%
Net income margin <sup>(3)(4)</sup>	15%	26ppc	
Non GAAP EBITDA margin <sup>(2)(4)</sup>	44%	5ppc	
Net income	\$551 million	N/M	
Non GAAP net income <sup>(2)</sup>	\$1,158 million	+20%	
Diluted earnings per ADS <sup>(5)</sup>	\$1.81	N/M	
Non GAAP diluted earnings per ADS <sup>(2)(5)</sup>	\$3.81	+20%	+19%
Net cash provided by operating activities	\$1,055 million	+101%	
Non GAAP free cash flow <sup>(2)</sup>	\$901 million	+128%	

<sup>(1)</sup> Results include Baxalta Inc. (Baxalta) (acquired on June 3, 2016), unless otherwise noted. Percentages compare to equivalent 2016 period. <sup>(2)</sup> The Non GAAP financial measures included within this release are explained on pages 27 – 28, and are reconciled to the most directly comparable financial measures prepared in accordance with US GAAP on pages 21 – 23. <sup>(3)</sup> US GAAP net income as a percentage of total revenues. <sup>(4)</sup> Percentage point change (ppc). <sup>(5)</sup> Diluted weighted average number of ordinary shares of 912 million.

### Product sales growth

- Delivered product sales growth of 7%, including robust demand for our Immunology franchise, up 32%.
- Successful early trajectory of MYDAYIS since U.S. launch on August 28, 2017, with over 3,000 physicians prescribing to over 11,000 patients as of October 17, 2017.
- Genetic Diseases was impacted by lower product sales for CINRYZE due to a product shortage resulting from a manufacturing interruption. The manufacturing issue has been addressed and production of CINRYZE resumed. Approximately \$100 million of product was shipped to customers in early October.
- Increasing demand for XIIDRA; 9% script growth since Q2 2017.

### Earnings growth

- Generated Non GAAP earnings per ADS of \$3.81, underscoring continued focus on commercial excellence and operating efficiency.
- Reported Non GAAP EBITDA margin of 44% for the quarter; on-track to achieve at least \$700 million in synergies by Year 3 as we continued to progress the Baxalta integration.
- Completed manufacturing network review; identified more than \$100 million in projected additional annual savings beginning in 2019. Expected to increase to \$300 million annually by 2023.

### Strong cash flow

- Strong operating cash flow enabled \$920 million reduction in Non GAAP net debt since June 30, 2017; remain on-track to achieve our year-end debt target.

## Product and Pipeline Highlights

### ***Regulatory updates***

- Submitted an application to the U.S. Food and Drug Administration (FDA) to enable a second source of CINRYZE production at an in-house manufacturing facility to enhance reliability of supply.
- Submitted lifitegrast Marketing Authorization Application for treatment of dry eye disease in Europe; Canadian approval anticipated by Q1 2018.
- Received FDA Fast Track Designation for SHP607 for the prevention of chronic lung disease in extremely premature infants.
- Positive opinion from Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending the marketing authorization for lyophilized ONCASPAR (pegaspargase), as a component of antineoplastic combination therapy in acute lymphoblastic leukemia (ALL) in all ages.
- Received FDA Orphan Drug Designation and Investigational New Drug (IND) status for SHP654 for the treatment of hemophilia A.
- Granted a label extension for FIRAZYR in Europe by the European Commission (EC), broadening its use to the treatment of acute attacks of HAE in adolescents and children aged 2 years and older.
- On track to file a Biologics License Application (BLA) for SHP643 in late 2017 or early 2018.
- On track to file a New Drug Application (NDA) for SHP555 in late Q4 2017.

### ***Clinical and business development updates***

- Strategic review of Neuroscience franchise on track; update planned for year end.
- Reported positive topline Phase 3 results for subcutaneous SHP616 Liquid in patients 12 years of age or older with symptomatic Hereditary Angioedema (HAE).
- Reported positive topline results for INTUNIV in Japan, evaluated in Phase 3 clinical trial in adults with ADHD.

## FINANCIAL SUMMARY - THIRD QUARTER 2017 COMPARED TO THIRD QUARTER 2016

### Revenues

- Product sales increased 7% to \$3,534 million (Q3 2016: \$3,315 million), primarily due to strong growth from our Immunology franchise, up 32%, Neuroscience franchise, up 12% and our Hematology franchise, up 4%. Product sales also benefited from a full quarter of Ophthalmics product sales. Growth was held back by the launch of generic competition for LIALDA and a supply constraint related to CINRYZE, which negatively impacted our Internal Medicine and Genetic Diseases franchises, down 24% and 7%, respectively.
- Royalties and other revenues increased 20% to \$164 million, primarily due to an increase in royalty streams acquired with Dyax and SENSIPAR royalties.

### Operating results

- Operating income was \$709 million (Q3 2016: operating loss of \$406 million). The increase was primarily due to lower expense relating to the unwind of inventory fair value adjustments and costs related to licensing arrangements, combined with higher revenues, partially offset by higher amortization of acquired intangible assets.
- Non GAAP operating income increased 19% to \$1,498 million (Q3 2016: \$1,254 million), primarily due to higher revenues and lower expenses as a percentage of total revenues driven by operating efficiencies which were impacted by the realization of Baxalta operating expense synergies.
- Non GAAP EBITDA margin as a percentage of total revenues increased to 44% (Q3 2016: 39%), primarily due to higher revenues and lower expenses as a percentage of total revenues, driven by operating efficiencies which were impacted by the realization of Baxalta operating expense synergies.

### Earnings per share (EPS)

- Diluted earnings per American Depositary Shares (ADS) were \$1.81 (Q3 2016: diluted losses per ADS of \$1.29). The increase is primarily due to higher operating income from lower expenses relating to the unwind of inventory fair value adjustments and costs related to licensing arrangements, combined with higher revenues.
- Non GAAP diluted earnings per ADS increased 20% to \$3.81 (Q3 2016: \$3.17), due to higher Non GAAP operating income primarily related to higher revenues and higher gross margin.

### Cash flows

- Net cash provided by operating activities increased 101% to \$1,055 million (Q3 2016: \$526 million), primarily due to strong cash receipts from higher sales and operating profitability, and lower Baxalta acquisition and integration payments. Also, Q3 2016 net cash provided by operating activities was negatively impacted by a payment associated with the termination of a biosimilar collaboration acquired with Baxalta.
- Non GAAP free cash flow increased 128% to \$901 million (Q3 2016: \$395 million), driven by the growth in net cash provided by operating activities noted above, combined with a decrease in capital expenditures of \$46 million.

### Debt

- Non GAAP net debt at September 30, 2017 decreased \$2,063 million since December 31, 2016, to \$20,376 million (December 31, 2016: \$22,439 million). The decrease was primarily due to a \$2,403 million net cash repayment of debt, partially offset by a lower cash balance. Non GAAP net debt represents aggregate long and short term borrowings of \$20,236 million, and capital leases of \$349 million, partially offset by cash and cash equivalents of \$209 million.

## OUTLOOK

We are reiterating our guidance from Q2 2017.

The guidance incorporates accelerated synergy capture as well as the impact of LIALDA generic competition. Our depreciation estimate for the year is \$450 - \$500 million, and we anticipate capital expenditures of \$800 - \$900 million.

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

<b>Full Year 2017</b>	<b>US GAAP Outlook</b>	<b>Non GAAP Outlook<sup>(1)</sup></b>
Total product sales	\$14.3 - \$14.6 billion	\$14.3 - \$14.6 billion
Royalties & other revenues	\$600 - \$700 million	\$600 - \$700 million
Gross margin as a percentage of total revenue <sup>(2)</sup>	67.5% - 69.5%	74.5% - 76.5%
Combined R&D and SG&A	\$5.3 - \$5.5 billion	\$4.9 - \$5.1 billion
Net interest/other	\$500 - \$600 million	\$500 - \$600 million
Effective tax rate	~7%	16% - 17%
Diluted earnings per ADS <sup>(3)</sup>	\$5.65 - \$6.05	\$14.80 - \$15.20

<sup>(1)</sup> For a list of items excluded from Non GAAP Outlook, refer to pages 27 - 28 of this release.

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

<sup>(3)</sup> See page 23 for a reconciliation between US GAAP diluted earnings per ADS and Non GAAP diluted earnings per ADS.

## RECENT DEVELOPMENTS

### Products

FIRAZYR for the treatment of HAE in Europe

- On October 26, 2017, Shire announced that the EC has approved a label extension for FIRAZYR, broadening its use to the treatment of acute attacks of HAE in adolescents and children aged 2 years and older.

INTUNIV for the treatment of attention deficit hyperactivity disorder (ADHD) in Japan

- On September 20, 2017, Shire and its partner in Japan, Shionogi & Co., Ltd, announced positive topline results for a Phase 3 study evaluating INTUNIV in adult patients with ADHD in Japan.

MYDAYIS for the treatment of ADHD

- On August 28, 2017, Shire announced that MYDAYIS was available by prescription in the United States. The FDA approved MYDAYIS on June 20, 2017 for patients 13 years and older with ADHD.

Lifitegrast for the treatment of dry eye disease (DED) in Europe

- On August 15, 2017, Shire announced that the Marketing Authorization Application for lifitegrast, submitted on August 7, 2017, was validated by the UK as the Reference Member State involved in the Decentralized Procedure.

### Pipeline

SHP654 for the treatment of hemophilia A

- On October 25, 2017, Shire announced that the FDA awarded Orphan Drug Designation to SHP654 (also designated as BAX 888), an investigational factor VIII (FVIII) gene therapy for the treatment of hemophilia A. The FDA also granted Shire IND status for SHP654.

SHP674 (ONCASPAR) for the treatment of acute lymphoblastic leukemia

- On October 12, 2017, Shire received a positive opinion from the CHMP recommending marketing authorization for Lyophilized ONCASPAR for use as a component of antineoplastic combination therapy in acute lymphoblastic leukemia (ALL) in all ages.

SHP607 for the treatment of complications of prematurity

- On September 12, 2017, Shire announced that the FDA has granted Fast Track designation for SHP607 for the prevention of chronic lung disease in extremely premature infants. SHP607 is currently in Phase 2 clinical development.

SHP616 for the treatment of HAE

- On September 11, 2017, Shire announced positive topline Phase 3 results for the SAHARA study that evaluated the efficacy and safety of subcutaneously administered C1 esterase inhibitor [human] Liquid for Injection in patients 12 years of age or older with symptomatic HAE.

### Board Changes

On August 21, 2017, Shire announced that Jeff Poulton, Chief Financial Officer, will be leaving Shire. The Board has commenced a formal search for a successor and Jeff will continue to serve in his current role as this search progresses. During this transition period, Jeff will remain on the Executive Committee and on the Board of Directors of Shire plc until the end of the year.

In addition, and following the announcement that Dominic Blakemore will be appointed Group Chief Executive of Compass Group PLC on April 1, 2018, the Board has approved the appointment of Sara Mathew as Chair of the Audit Compliance & Risk Committee to take place with immediate effect. Dominic Blakemore will remain a member of the Audit Compliance & Risk Committee.

## 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 / 9:00 EDT on October 27, 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:	<a href="#">Click here</a>
Password/Conf ID:	31097524#
Live Webcast:	<a href="#">Click here</a>

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 THIRD QUARTER 2017 FINANCIAL RESULTS COMPARED TO THIRD QUARTER 2016

### 1. Product sales

Product sales increased 7% to \$3,534 million (Q3 2016: \$3,315 million).

(in millions)				Total Sales Year on year growth	
				Reported	Non GAAP CER
Product sales by franchise	U.S. Sales	International Sales	Total Sales		
HEMOPHILIA	\$ 357.5	\$ 367.8	\$ 725.3	+3%	+3%
INHIBITOR THERAPIES	70.6	120.1	190.7	+5%	+4%
<b>Hematology</b>	<b>428.1</b>	<b>487.9</b>	<b>916.0</b>	+4%	+3%
IMMUNOGLOBULIN THERAPIES	486.6	118.5	605.1	+28%	+28%
BIO THERAPEUTICS	86.3	110.3	196.6	+47%	+45%
<b>Immunology</b>	<b>572.9</b>	<b>228.8</b>	<b>801.7</b>	+32%	+32%
VYVANSE	476.8	61.6	538.4	+5%	+5%
ADDERALL XR	99.4	6.6	106.0	+32%	+32%
MYDAYIS	10.2	—	10.2	N/A	N/A
Other Neuroscience	6.7	29.8	36.5	+56%	+53%
<b>Neuroscience</b>	<b>593.1</b>	<b>98.0</b>	<b>691.1</b>	+12%	+12%
FIRAZYR	173.6	21.9	195.5	+34%	+33%
ELAPRASE	41.4	111.5	152.9	+4%	+1%
REPLAGAL	—	117.2	117.2	-1%	-4%
VPRIV	37.5	52.1	89.6	+2%	+1%
CINRYZE	46.2	10.7	56.9	-66%	-66%
KALBITOR	16.0	—	16.0	+44%	+44%
<b>Genetic Diseases</b>	<b>314.7</b>	<b>313.4</b>	<b>628.1</b>	-7%	-8%
LIALDA/MEZAVANT	61.4	25.3	86.7	-58%	-59%
GATTEX/REVESTIVE	72.6	12.3	84.9	+46%	+45%
PENTASA	72.1	—	72.1	-16%	-16%
NATPARA	39.1	—	39.1	+68%	+68%
Other Internal Medicine	12.0	56.2	68.2	-22%	-24%
<b>Internal Medicine</b>	<b>257.2</b>	<b>93.8</b>	<b>351.0</b>	-24%	-25%
<b>Ophthalmics</b>	<b>77.4</b>	<b>—</b>	<b>77.4</b>	N/M	N/M
<b>Oncology</b>	<b>47.2</b>	<b>21.3</b>	<b>68.5</b>	+24%	+22%
<b>Total product sales</b>	<b>\$ 2,290.6</b>	<b>\$ 1,243.2</b>	<b>\$ 3,533.8</b>	+7%	+6%

#### Hematology

Hematology product sales increased 4%, with growth in both our hemophilia and inhibitor therapies products.

Growth across the portfolio was driven by underlying demand in our international markets, which also benefited from the timing of large orders. U.S. sales were flat year over year, as increased demand, primarily related to our FVII products, was offset by the impact of destocking in Q3 2017 compared to stocking in Q3 2016.



## **Immunology**

Immunology product sales increased 32% with strong growth from both our immunoglobulin therapies and bio therapeutics products.

The U.S. benefited from growth in demand and stocking for GAMMAGARD liquid, and increasing demand for our subcutaneous portfolio. International growth was primarily due to the timing of large orders and strong underlying performance in all regions.

## **Neuroscience**

Neuroscience product sales increased 12%, primarily driven by VYVANSE and ADDERALL XR.

VYVANSE sales increased 5%, primarily due to the benefit of a price increase taken since Q3 2016, increased demand resulting from U.S. ADHD market growth and solid performance in our international markets. ADDERALL XR sales increased 32%, primarily due to stocking in Q3 2017 compared to destocking in the prior year.

MYDAYIS, which was made available to patients on August 28, 2017, contributed \$10 million of product sales.

## **Genetic Diseases**

Genetic Diseases product sales decreased 7%, primarily due to the impact of a CINRYZE supply constraint, which was partially offset by FIRAZYR growth.

CINRYZE sales decreased 66% due to supply constraints caused by a manufacturing interruption that was experienced during the quarter. The issue has been addressed, and production has resumed. Approximately \$100 million of product was shipped to customers in early October. We continue to work to stabilize CINRYZE manufacturing, however supply constraints may continue until we secure a second source of production. Subject to FDA approval, we expect to add CINRYZE in-house production capabilities in early Q1 2018.

FIRAZYR sales increased 34%, due to increased patient demand and stocking, in part due to the CINRYZE supply constraints.

## **Internal Medicine**

Internal Medicine product sales decreased 24%, as the impact of LIALDA generic competition was partially offset by growth from GATTEX/REVESTIVE and NATPARA.

LIALDA/MEZAVANT sales decreased 58%, due to the impact of generic competition in Q3 2017. An authorized generic was launched in the second half of Q3 2017.

GATTEX/REVESTIVE and NATPARA continued to perform well with sales increasing 46% and 68%, respectively, primarily due to an increase in the numbers of patients on therapy.

## **Ophthalmics**

Ophthalmics product sales relate to XIIDRA, which was made available to patients starting on August 29, 2016. XIIDRA contributed \$77 million of product sales with 9% prescription growth since Q2 2017.

## **Oncology**

Oncology product sales increased 24%. Growth was driven by sales of ONCASPAR and ONIVYDE, the latter of which was approved in the EU on October 18, 2016.

## 2. Royalties and other revenues

(in millions)	Revenue	Year on year growth	
		Reported	Non GAAP CER
SENSIPAR royalties	\$ 42.8	+11%	+11%
3TC and ZEFFIX royalties	16.1	-1%	-1%
FOSRENOL royalties	14.3	+4%	+12%
ADDERALL XR royalties	7.7	+64%	+64%
Other royalties and revenues	82.9	+31%	+28%
Total royalties and other revenues	\$ 163.8	+20%	+19%

Royalties and other Revenues increased 20%, primarily due to an increase in royalty streams acquired with Dyax and SENSIPAR royalties.

## 3. Financial details

### Cost of sales

(in millions)	Q3 2017	% of total revenues	Q3 2016	% of total revenues
	Cost of sales (US GAAP)	\$ 1,001.4	27%	\$ 1,736.2
Expense related to the unwind of inventory fair value adjustments	(63.3)		(803.8)	
Inventory write-down relating to the closure of a facility	—		(11.6)	
Depreciation	(70.1)		(54.5)	
Non GAAP cost of sales	\$ 868.0	23%	\$ 866.3	25%

Cost of sales as a percentage of total revenues decreased to 27%, primarily due to lower expense related to the unwind of inventory fair value adjustments.

Non GAAP cost of sales as a percentage of total revenues decreased to 23%, primarily driven by operating efficiencies and the realization of synergies from the acquisition of Baxalta.

### R&D

(in millions)	Q3 2017	% of total revenues	Q3 2016	% of total revenues
	R&D (US GAAP)	\$ 402.8	11%	\$ 511.1
Costs relating to license arrangements	—		(110.0)	
Depreciation	(10.8)		(9.0)	
Non GAAP R&D	\$ 392.0	11%	\$ 392.1	11%

R&D expenditure decreased by \$108 million, or 21%, primarily due to lower costs relating to license arrangements.

Non GAAP R&D expenditure, and expense as a percentage of total revenues, remained consistent with Q3 2016, as an increase in costs relating to our late stage pipeline was offset by savings on discontinued programs.

## SG&A

(in millions)	Q3 2017	% of total revenues	Q3 2016	% of total revenues
SG&A (US GAAP)	\$ 859.7	23%	\$ 875.6	25%
Legal and litigation costs	(1.0)		0.5	
Depreciation	(39.0)		(29.6)	
Non GAAP SG&A	\$ 819.7	22%	\$ 846.5	25%

SG&A expenditure decreased by \$16 million, or 2%, primarily due to the realization of synergies from the acquisition of Baxalta and lower XIIDRA marketing spend, which was partially offset by MYDAYIS launch costs and increased depreciation expense.

Non GAAP SG&A expenditure decreased by \$27 million, or 3%, primarily due to the realization of synergies from the acquisition of Baxalta and lower XIIDRA marketing spend, which was partially offset by MYDAYIS launch costs. Non GAAP SG&A as a percentage of total revenues decreased 3 percentage points.

### Amortization of acquired intangible assets

Shire recorded amortization of acquired intangible assets of \$482 million (Q3 2016: \$355 million), primarily related to intangible assets acquired with Baxalta and the acceleration of CINRYZE amortization following positive SHP643 Phase 3 results.

### Integration and acquisition costs

In Q3 2017, Shire recorded integration and acquisition costs of \$237 million, primarily relating to the Baxalta transaction. Costs included asset impairment charges, employee severance, the acceleration of stock compensation, third-party professional fees and expenses associated with facility consolidations.

In Q3 2016, Shire recorded integration and acquisition costs of \$285 million, primarily relating to the Baxalta and Dyax transactions. Costs included employee severance, the acceleration of stock compensation, third-party professional fees, contract terminations and other transaction-related fees.

### Reorganization costs

In Q3 2017, Shire recorded reorganization costs of \$5 million. In Q3 2016, Shire recorded reorganization costs of \$101 million, primarily related to the closure of a facility at the Los Angeles manufacturing site.

### Other expense, net

(in millions)	Q3 2017	Q3 2016
Other expense, net (US GAAP)	\$ (140.5)	\$ (191.3)
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	1.9	47.4
Loss on sale of long term investments	4.3	—
Non GAAP Other expense, net	\$ (134.3)	\$ (143.9)

Other expense, net decreased by \$51 million, primarily due to lower amortization of one-time upfront borrowing costs for Baxalta and Dyax.

Non GAAP Other expense, net decreased by \$10 million.

## Taxation

(in millions)	Q3 2017	Effective tax rate	Q3 2016	Effective tax rate
Income tax expense (US GAAP)	\$ (13.5)	2%	\$ 229.6	(38%)
Non GAAP tax adjustments	(189.0)		(377.3)	
Non GAAP Income tax expense	\$ (202.5)	15%	\$ (147.7)	13%

The effective tax rate on US GAAP income in Q3 2017 was 2% (Q3 2016: -38%) and on a Non GAAP basis was 15% (Q3 2016: 13%).

The effective rate in Q3 2017 on US GAAP income from continuing operations is low, primarily due to the combined impact of the relative quantum of profit before tax for the period by jurisdiction as well as significant acquisition and integration costs. Additionally, certain discrete events occurred during Q3 2017 which contributed to the low effective tax rate, including a tax benefit associated with filing of the US tax returns and the reversal of prior period income tax reserves.

### Discontinued operations

The loss from discontinued operations in Q3 2017 was less than \$1 million, net of taxes. The loss in Q3 2016 was \$18 million, net of taxes, primarily due to the establishment of legal contingencies related to the divested DERMAGRAFT business.

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## Unaudited US GAAP Consolidated Balance Sheets

(in millions, except par value of shares)

	September 30, 2017	December 31, 2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 209.3	\$ 528.8
Restricted cash	34.3	25.6
Accounts receivable, net	2,840.7	2,616.5
Inventories	3,427.3	3,562.3
Prepaid expenses and other current assets	779.9	806.3
Total current assets	<u>7,291.5</u>	<u>7,539.5</u>
Non-current assets:		
Investments	199.7	191.6
Property, plant and equipment (PP&E), net	6,579.5	6,469.6
Goodwill	19,718.4	17,888.2
Intangible assets, net	33,350.3	34,697.5
Deferred tax asset	94.6	96.7
Other non-current assets	242.5	152.3
Total assets	<u>\$ 67,476.5</u>	<u>\$ 67,035.4</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,870.5	\$ 4,312.4
Short term borrowings and capital leases	2,629.2	3,068.0
Other current liabilities	961.4	362.9
Total current liabilities	<u>7,461.1</u>	<u>7,743.3</u>
Non-current liabilities:		
Long term borrowings and capital leases	17,956.0	19,899.8
Deferred tax liability	7,681.7	8,322.7
Other non-current liabilities	1,723.1	2,121.6
Total liabilities	<u>34,821.9</u>	<u>38,087.4</u>
Equity:		
Common stock of 5p par value; 1,500 shares authorized; and 915.9 shares issued and outstanding (2016: 1,500 shares authorized; and 912.2 shares issued and outstanding)	81.5	81.3
Additional paid-in capital	25,020.9	24,740.9
Treasury stock: 8.4 shares (2016: 9.1 shares)	(283.0)	(301.9)
Accumulated other comprehensive income/(loss)	969.1	(1,497.6)
Retained earnings	6,866.1	5,925.3
Total equity	<u>32,654.6</u>	<u>28,948.0</u>
Total liabilities and equity	<u>\$ 67,476.5</u>	<u>\$ 67,035.4</u>

## Unaudited US GAAP Consolidated Statements of Operations

(in millions)

	3 months ended September 30,		9 months ended September 30,	
	2017	2016	2017	2016
<b>Revenues:</b>				
Product sales	\$ 3,533.8	\$ 3,315.4	\$ 10,537.9	\$ 7,264.8
Royalties & other revenues	163.8	136.7	477.8	325.7
<b>Total revenues</b>	<b>3,697.6</b>	<b>3,452.1</b>	<b>11,015.7</b>	<b>7,590.5</b>
<b>Costs and expenses:</b>				
Cost of sales	1,001.4	1,736.2	3,437.3	2,762.9
Research and development	402.8	511.1	1,324.5	1,023.0
Selling, general and administrative	859.7	875.6	2,647.7	2,025.8
Amortization of acquired intangible assets	482.4	354.9	1,280.5	702.5
Integration and acquisition costs	237.0	284.5	696.7	738.6
Reorganization costs	5.4	101.4	24.5	115.7
Loss/(gain) on sale of product rights	0.3	(5.7)	(0.4)	(12.2)
<b>Total operating expenses</b>	<b>2,989.0</b>	<b>3,858.0</b>	<b>9,410.8</b>	<b>7,356.3</b>
<b>Operating income/(loss) from continuing operations</b>	<b>708.6</b>	<b>(405.9)</b>	<b>1,604.9</b>	<b>234.2</b>
Interest income	1.5	9.3	5.7	11.9
Interest expense	(141.8)	(186.9)	(425.4)	(318.8)
Other (expense)/income, net	(0.2)	(13.7)	6.8	(16.2)
<b>Total other expense, net</b>	<b>(140.5)</b>	<b>(191.3)</b>	<b>(412.9)</b>	<b>(323.1)</b>
Income/(loss) from continuing operations before income taxes and equity in (losses)/earnings of equity method investees	568.1	(597.2)	1,192.0	(88.9)
Income taxes	(13.5)	229.6	(44.6)	218.4
Equity in (losses)/earnings of equity method investees, net of taxes	(3.4)	(0.9)	0.1	(1.9)
<b>Income/(loss) from continuing operations, net of taxes</b>	<b>551.2</b>	<b>(368.5)</b>	<b>1,147.5</b>	<b>127.6</b>
(Loss)/gain from discontinued operations, net of taxes	(0.4)	(18.3)	18.6	(257.5)
<b>Net income/(loss)</b>	<b>\$ 550.8</b>	<b>\$ (386.8)</b>	<b>\$ 1,166.1</b>	<b>\$ (129.9)</b>

## Unaudited US GAAP Consolidated Statements of Operations (continued)

(in millions, except per share amounts)

	3 months ended September 30,		9 months ended September 30,	
	2017	2016	2017	2016
<b>Earnings/(loss) per Ordinary Share – basic</b>				
Earnings/(loss) from continuing operations	\$ 0.61	\$ (0.41)	\$ 1.27	\$ 0.18
(Loss)/gain from discontinued operations	(0.00)	(0.02)	0.02	(0.36)
Earnings/(loss) per Ordinary Share – basic	\$ 0.61	\$ (0.43)	\$ 1.29	\$ (0.18)
Earnings/(loss) per ADS – basic	\$ 1.82	\$ (1.29)	\$ 3.86	\$ (0.54)
<b>Earnings/(loss) per Ordinary Share – diluted</b>				
Earnings/(loss) from continuing operations	\$ 0.60	\$ (0.41)	\$ 1.26	\$ 0.18
(Loss)/earnings from discontinued operations	(0.00)	(0.02)	0.02	(0.36)
Earnings/(loss) per Ordinary Share – diluted	\$ 0.60	\$ (0.43)	\$ 1.28	\$ (0.18)
Earnings/(loss) per ADS – diluted	\$ 1.81	\$ (1.29)	\$ 3.84	\$ (0.54)
<b>Weighted average number of shares:</b>				
Basic	907.2	900.2	905.9	725.5
Diluted	911.6	900.2	912.1	725.5



## Unaudited US GAAP Consolidated Statements of Cash Flows

(in millions)

	3 months ended September 30,		9 months ended September 30,	
	2017	2016	2017	2016
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>				
Net income/(loss)	\$ 550.8	\$ (386.8)	\$ 1,166.1	\$ (129.9)
Adjustments to reconcile net income/(loss) to net cash provided by operating activities:				
Depreciation and amortization	602.3	448.0	1,644.0	877.8
Share based compensation	53.3	74.8	159.7	269.6
Amortization of deferred financing fees	4.1	71.6	10.9	121.7
Expense related to the unwind of inventory fair value adjustments	63.3	803.8	688.7	1,097.3
Change in deferred taxes	(99.1)	(217.7)	(392.4)	(546.9)
Change in fair value of contingent consideration	(3.4)	10.2	144.3	(34.8)
Impairment of PP&E and intangible assets	114.0	89.2	167.6	98.1
Other, net	73.5	52.9	88.3	35.3
Changes in operating assets and liabilities:				
Increase in accounts receivable	(120.0)	(230.2)	(301.5)	(411.2)
Increase in sales deduction accrual	36.9	41.8	94.0	108.2
Increase in inventory	(73.6)	(111.6)	(245.2)	(228.0)
(Increase)/decrease in prepayments and other assets	(34.2)	(92.9)	70.4	(66.4)
(Decrease)/increase in accounts payable and other liabilities	(112.7)	(27.5)	(557.8)	315.2
Net cash provided by operating activities	<u>1,055.2</u>	<u>525.6</u>	<u>2,737.1</u>	<u>1,506.0</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>				
Purchases of PP&E and long term investments	(174.4)	(223.4)	(565.5)	(402.5)
Purchases of businesses, net of cash acquired	—	—	—	(17,476.2)
Proceeds from sale of investments	7.5	0.6	48.1	0.6
Movements in restricted cash	—	1.1	(8.6)	68.3
Other, net	31.6	(4.8)	34.8	(1.5)
Net cash used in investing activities	<u>(135.3)</u>	<u>(226.5)</u>	<u>(491.2)</u>	<u>(17,811.3)</u>

## Unaudited US GAAP Consolidated Statements of Cash Flows (continued)

(in millions)

	3 months ended September 30,		9 months ended September 30,	
	2017	2016	2017	2016
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>				
Proceeds from revolving line of credit, long term and short term borrowings	<b>1,149.7</b>	12,847.3	<b>3,261.6</b>	31,742.3
Repayment of revolving line of credit, long term and short term borrowings	<b>(2,136.6)</b>	(13,132.6)	<b>(5,664.5)</b>	(14,632.9)
Payment of dividend	—	—	<b>(234.7)</b>	(130.2)
Debt issuance costs	—	(58.7)	—	(171.0)
Proceeds from exercise of options	<b>12.7</b>	137.1	<b>92.2</b>	137.2
Other, net	<b>(2.2)</b>	(56.7)	<b>(26.2)</b>	(44.8)
Net cash (used in)/provided by financing activities	<b>(976.4)</b>	(263.6)	<b>(2,571.6)</b>	16,900.6
Effect of foreign exchange rate changes on cash and cash equivalents	<b>2.1</b>	(0.3)	<b>6.2</b>	(2.2)
Net (decrease)/increase in cash and cash equivalents	<b>(54.4)</b>	35.2	<b>(319.5)</b>	593.1
Cash and cash equivalents at beginning of period	<b>263.7</b>	693.4	<b>528.8</b>	135.5
Cash and cash equivalents at end of period	<b>\$ 209.3</b>	\$ 728.6	<b>\$ 209.3</b>	\$ 728.6

## Selected Notes to the Unaudited US GAAP Financial Statements

### (1) Earnings Per Share (EPS)

(in millions)

	3 months ended September 30,		9 months ended September 30,	
	2017	2016	2017	2016
Income/(loss) from continuing operations	\$ 551.2	\$ (368.5)	\$ 1,147.5	\$ 127.6
(Loss)/gain from discontinued operations	(0.4)	(18.3)	18.6	(257.5)
Numerator for EPS	\$ 550.8	\$ (386.8)	\$ 1,166.1	\$ (129.9)
Weighted average number of shares:				
Basic	907.2	900.2	905.9	725.5
Effect of dilutive shares:				
Share based awards to employees	4.4	—	6.2	—
Diluted	911.6	900.2	912.1	725.5

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

Share based awards to employees	16.2	14.6	14.8	9.7
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## Selected Notes to the Unaudited US GAAP Financial Statements

### (2) Analysis of revenues

(in millions)

	3 months ended September 30,		9 months ended September 30,	
	2017	2016	2017	2016
<b>Product sales by franchise</b>				
HEMOPHILIA	\$ 725.3	\$ 702.4	\$ 2,119.6	\$ 978.0
INHIBITOR THERAPIES	190.7	181.7	631.9	255.7
<b>Hematology</b>	<b>916.0</b>	884.1	<b>2,751.5</b>	1,233.7
IMMUNOGLOBULIN THERAPIES	605.1	472.5	1,613.9	610.7
BIO THERAPEUTICS	196.6	134.0	546.7	185.3
<b>Immunology</b>	<b>801.7</b>	606.5	<b>2,160.6</b>	796.0
VYVANSE	538.4	512.6	1,620.3	1,539.5
ADDERALL XR	106.0	80.5	242.3	281.1
MYDAYIS	10.2	—	25.9	—
Other Neuroscience	36.5	23.4	91.3	81.2
<b>Neuroscience</b>	<b>691.1</b>	616.5	<b>1,979.8</b>	1,901.8
FIRAZYR	195.5	146.3	461.4	411.3
ELAPRASE	152.9	146.7	454.5	424.3
REPLAGAL	117.2	118.9	349.0	340.5
VPRIV	89.6	87.7	257.3	259.3
CINRYZE	56.9	165.4	458.7	502.6
KALBITOR	16.0	11.1	48.3	39.2
<b>Genetic Diseases</b>	<b>628.1</b>	676.1	<b>2,029.2</b>	1,977.2
LIALDA/MEZAVANT	86.7	208.6	469.6	570.3
GATTEX/REVESTIVE	84.9	58.1	229.2	154.3
PENTASA	72.1	85.4	224.5	222.3
NATPARA	39.1	23.3	103.3	58.8
Other Internal Medicine	68.2	87.3	227.5	260.6
<b>Internal Medicine</b>	<b>351.0</b>	462.7	<b>1,254.1</b>	1,266.3
<b>Ophthalmics</b>	<b>77.4</b>	14.1	<b>173.4</b>	14.1
<b>Oncology</b>	<b>68.5</b>	55.4	<b>189.3</b>	75.7
<b>Total product sales</b>	<b>3,533.8</b>	3,315.4	<b>10,537.9</b>	7,264.8
<b>Royalties and other revenues</b>				
SENSIPAR royalties	42.8	38.7	128.1	112.2
3TC and ZEFFIX royalties	16.1	16.2	38.8	43.3
FOSRENOL royalties	14.3	13.7	35.0	34.3
ADDERALL XR royalties	7.7	4.7	33.6	15.7
Other Royalties and revenues	82.9	63.4	242.3	120.2
<b>Total royalties and other revenues</b>	<b>163.8</b>	136.7	<b>477.8</b>	325.7
<b>Total revenues</b>	<b>\$ 3,697.6</b>	\$ 3,452.1	<b>\$ 11,015.7</b>	\$ 7,590.5

## Non GAAP reconciliations

(in millions)

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

	3 months ended September 30,		9 months ended September 30,	
	2017	2016	2017	2016
<b>US GAAP net income/(loss)</b>	<b>\$ 550.8</b>	<b>\$ (386.8)</b>	<b>\$ 1,166.1</b>	<b>\$ (129.9)</b>
Add back/(deduct):				
Loss/(gain) from discontinued operations, net of tax	0.4	18.3	(18.6)	257.5
Equity in losses/(earnings) of equity method investees, net of taxes	3.4	0.9	(0.1)	1.9
Income taxes	13.5	(229.6)	44.6	(218.4)
Other expense, net	140.5	191.3	412.9	323.1
US GAAP operating income from continuing operations	708.6	(405.9)	1,604.9	234.2
Add back/(deduct) Non GAAP adjustments:				
Expense related to the unwind of inventory fair value adjustments	63.3	803.8	688.7	1,097.3
Impairment of acquired intangible assets	—	—	20.0	8.9
Costs relating to license arrangements	—	110.0	123.7	110.0
Legal and litigation costs	1.0	(0.5)	8.6	16.1
Amortization of acquired intangible assets	482.4	354.9	1,280.5	702.5
Integration and acquisition costs	237.0	284.5	696.7	738.6
Reorganization costs	5.4	101.4	24.5	115.7
Loss/(gain) on sale of product rights	0.3	(5.7)	(0.4)	(12.2)
Depreciation	119.9	93.1	363.5	175.3
Other Non GAAP adjustments	—	11.6	(4.0)	11.6
<b>Non GAAP EBITDA</b>	<b>1,617.9</b>	<b>1,347.2</b>	<b>4,806.7</b>	<b>3,198.0</b>
Depreciation	(119.9)	(93.1)	(363.5)	(175.3)
<b>Non GAAP operating income</b>	<b>\$ 1,498.0</b>	<b>\$ 1,254.1</b>	<b>\$ 4,443.2</b>	<b>\$ 3,022.7</b>
<b>Net income margin<sup>(1)</sup></b>	<b>15%</b>	<b>(11)%</b>	<b>11%</b>	<b>(2)%</b>
<b>Non GAAP EBITDA margin<sup>(2)</sup></b>	<b>44%</b>	<b>39 %</b>	<b>44%</b>	<b>42 %</b>

<sup>(1)</sup> Net income as a percentage of total revenues.

<sup>(2)</sup> Non GAAP EBITDA as a percentage of total revenues.

Reconciliation of revenues to Non GAAP gross margin:

	3 months ended September 30,		9 months ended September 30,	
	2017	2016	2017	2016
<b>Revenues</b>	<b>\$ 3,697.6</b>	<b>\$ 3,452.1</b>	<b>\$ 11,015.7</b>	<b>\$ 7,590.5</b>
Cost of sales (US GAAP)	(1,001.4)	(1,736.2)	(3,437.3)	(2,762.9)
<b>US GAAP gross margin</b>	<b>2,696.2</b>	<b>1,715.9</b>	<b>7,578.4</b>	<b>4,827.6</b>
Add back Non GAAP adjustments:				
Expense related to the unwind of inventory fair value adjustments	63.3	803.8	688.7	1,097.3
Inventory write-down relating to the closure of a facility	—	11.6	—	11.6
Depreciation	70.1	54.5	209.2	85.2
<b>Non GAAP gross margin</b>	<b>\$ 2,829.6</b>	<b>\$ 2,585.8</b>	<b>\$ 8,476.3</b>	<b>\$ 6,021.7</b>
<b>Non GAAP gross margin %<sup>(1)</sup></b>	<b>76.5%</b>	<b>74.9%</b>	<b>76.9%</b>	<b>79.3%</b>

<sup>(1)</sup> 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 September 30,		9 months ended September 30,	
	2017	2016	2017	2016
<b>US GAAP net income/(loss)</b>	<b>\$ 550.8</b>	<b>\$ (386.8)</b>	<b>\$ 1,166.1</b>	<b>\$ (129.9)</b>
Expense related to the unwind of inventory fair value adjustments	63.3	803.8	688.7	1,097.3
Impairment of acquired intangible assets	—	—	20.0	8.9
Costs relating to license arrangements	—	110.0	123.7	110.0
Legal and litigation costs	1.0	(0.5)	8.6	16.1
Amortization of acquired intangible assets	482.4	354.9	1,280.5	702.5
Integration and acquisition costs	237.0	284.5	696.7	738.6
Reorganization costs	5.4	101.4	24.5	115.7
Loss/(gain) on sale of product rights	0.3	(5.7)	(0.4)	(12.2)
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	1.9	47.4	5.4	91.5
Loss/(gain) on sale of long term investments	4.3	—	(8.9)	6.0
Loss/(gain) from discontinued operations	0.4	24.0	(29.6)	358.6
Other Non GAAP adjustments	—	11.6	(4.0)	11.6
Non GAAP tax adjustments	(189.0)	(383.0)	(576.5)	(748.7)
<b>Non GAAP net income</b>	<b>\$ 1,157.8</b>	<b>\$ 961.6</b>	<b>\$ 3,394.8</b>	<b>\$ 2,366.0</b>

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

	3 months ended September 30,		9 months ended September 30,	
	2017	2016	2017	2016
<b>US GAAP diluted earnings/(losses) per ADS</b>	<b>\$ 1.81</b>	<b>\$ (1.29)</b>	<b>\$ 3.84</b>	<b>\$ (0.54)</b>
Expense related to the unwind of inventory fair value adjustments	0.21	2.66	2.26	4.51
Impairment of acquired intangible assets	—	—	0.07	0.04
Costs relating to license arrangements	—	0.36	0.41	0.45
Legal and litigation costs	0.00	0.00	0.03	0.07
Amortization of acquired intangible assets	1.59	1.17	4.21	2.88
Integration and acquisition costs	0.78	0.94	2.29	3.03
Reorganization costs	0.02	0.33	0.08	0.47
Loss/(gain) on sale of product rights	0.00	(0.02)	(0.00)	(0.05)
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	0.01	0.16	0.02	0.38
Loss/(gain) on sale of long term investments	0.01	—	(0.03)	0.02
Loss/(gain) from discontinued operations	0.00	0.08	(0.10)	1.47
Other Non GAAP adjustments	—	0.04	(0.01)	0.05
Non GAAP tax adjustments	(0.62)	(1.26)	(1.90)	(3.07)
<b>Non GAAP diluted earnings per ADS</b>	<b>\$ 3.81</b>	<b>\$ 3.17</b>	<b>\$ 11.17</b>	<b>\$ 9.71</b>

## Non GAAP reconciliations

(in millions, except per ADS amounts)

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

	3 months ended September 30,		9 months ended September 30,	
	2017	2016	2017	2016
<b>Net cash provided by operating activities</b>	<b>\$ 1,055.2</b>	<b>\$ 525.6</b>	<b>\$ 2,737.1</b>	<b>\$ 1,506.0</b>
Capital expenditure	(174.4)	(220.8)	(565.5)	(399.6)
Payments relating to license arrangements	20.0	90.0	40.0	90.0
<b>Non GAAP free cash flow</b>	<b>\$ 900.8</b>	<b>\$ 394.8</b>	<b>\$ 2,211.6</b>	<b>\$ 1,196.4</b>

Non GAAP net debt comprises:

	September 30, 2017	December 31, 2016
Cash and cash equivalents	\$ 209.3	\$ 528.8
Long term borrowings (excluding capital leases)	(17,613.9)	(19,552.6)
Short term borrowings (excluding capital leases)	(2,622.2)	(3,061.6)
Capital leases	(349.1)	(353.6)
<b>Non GAAP net debt</b>	<b>\$ (20,375.9)</b>	<b>\$ (22,439.0)</b>

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
<b>US GAAP diluted earnings per ADS</b>	<b>\$ 5.65</b>	<b>\$ 6.05</b>
Expense related to the unwind of inventory fair value adjustments		2.42
Impairment of acquired intangible assets		0.07
Costs relating to licensing arrangements		0.46
Legal and litigation costs		0.04
Amortization of acquired intangible assets		5.64
Integration and acquisition costs		2.98
Reorganization costs		0.10
Amortization of one-time upfront borrowing costs for Baxalta and Dyax		0.02
Loss from discontinued operations		(0.10)
Gain on sale of long term investments		(0.01)
Other Non-GAAP adjustments		(0.04)
Non GAAP tax adjustments		(2.43)
<b>Non GAAP diluted earnings per ADS</b>	<b>\$ 14.80</b>	<b>\$ 15.20</b>

## **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 global leader in serving patients with rare diseases. We strive to develop best-in-class therapies across a core of rare disease areas including hematology, immunology, genetic diseases, neuroscience, and internal medicine with growing therapeutic areas in ophthalmics and oncology. Our diversified capabilities enable us to reach patients in more than 100 countries who are struggling to live their lives to the fullest.

We feel a strong sense of urgency to address unmet medical needs and work tirelessly to improve people's lives with medicines that have a meaningful impact on patients and all who support them on their journey.

[www.shire.com](http://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 has increased its borrowing costs and may decrease its business flexibility; 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 21 to 23.

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 September 30, 2017 were \$1.31:£1.00 and \$1.17:€1.00 (2016: \$1.32:£1.00 and \$1.11:€1.00). Average exchange rates used by Shire for the nine months ended September 30, 2017 were \$1.28:£1.00 and \$1.11:€1.00 (2016: \$1.40:£1.00 and \$1.11:€1.00).

## **TRADEMARKS**

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