

## Shire delivers strong Q2 2016 revenue growth; upgrades outlook

*Integration on track; operating cost synergy expectations increased*

*Pipeline progression continues with FDA approval of XIIDRA for dry eye disease*

**August 2, 2016** – Shire plc (“Shire”) (LSE: SHP, NASDAQ: SHPG) announces unaudited results for the three months ended June 30, 2016, inclusive of the Baxalta transaction that closed on June 3, 2016.

Financial Highlights	Q2 2016 <sup>(1)</sup>	Growth <sup>(1)</sup>	Non GAAP CER <sup>(1)(2)</sup>
Product sales	\$2,322 million	+57%	+58%
Product sales excluding Baxalta products	\$1,763 million	+19%	+20%
Total revenues	\$2,429 million	+56%	+57%
US GAAP operating income from continuing operations	\$96 million	(27%)	
Non GAAP operating income <sup>(2)</sup>	\$972 million	+58%	+57%
US GAAP net income margin <sup>(3)</sup>	(7%)	(17pps) <sup>(4)</sup>	
Non GAAP EBITDA margin <sup>(2)</sup>	40%	+1pps	
US GAAP net loss	(\$162 million)	(202%)	
Non GAAP net income <sup>(2)</sup>	\$773 million	+48%	
US GAAP diluted losses per ADS	(\$0.71)	(188%)	
Non GAAP diluted earnings per ADS <sup>(2)</sup>	\$3.38	+29%	+28%
US GAAP net cash provided by operating activities	\$591 million	+31%	
Non GAAP cash generation <sup>(2)</sup>	\$853 million	+69%	
Non GAAP free cash flow <sup>(2)</sup>	\$464 million	+7%	

<sup>(1)</sup> Results include Baxalta Inc. (“Baxalta”) (acquired on June 3, 2016) and Dyax Corp. (“Dyax”) (acquired on January 22, 2016). Percentages compare to equivalent 2015 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 22 – 23.

<sup>(3)</sup> US GAAP net income as a percentage of total revenues.

<sup>(4)</sup> Percentage point change (“pps”).

### Q2 2016 and Recent Highlights:

- Strong topline growth delivered across the business; legacy Shire product sales increased 19% in Q2 2016, legacy Baxalta product sales increased 12% on a pro forma basis in Q2 2016.
- Achieved significant progress on the Baxalta integration with upgraded guidance; operating cost synergy expectations increased by 40% to at least \$700 million in year three post close.
- Obtained FDA approval of Shire’s first medicine in ophthalmics, XIIDRA (lifitegrast ophthalmic solution) 5%; U.S. launch expected in Q3 2016.
- Strong pipeline progress across many late stage product candidates:
  - Received a positive opinion from the Committee for Medicinal Products for Human Use (“CHMP”) recommending marketing authorization for ONIVYDE for treatment of adult patients with metastatic adenocarcinoma of the pancreas who have progressed following gemcitabine-based therapy.
  - Completed decentralized procedure to support European approval of CUVITRU, expanding therapeutic options within our Immunology portfolio.
  - Reported encouraging topline efficacy and safety data for SHP465 in adults with ADHD supporting an FDA resubmission planned by the end of 2016.
  - Expanded our gastrointestinal portfolio with in-licensing from Pfizer of late-stage asset, SHP647 (formerly known as PF-00547659), for the potential treatment of moderate-to-severe Inflammatory Bowel Disease (“IBD”).

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

“The second quarter marked an important milestone in Shire’s history, as we completed the combination with Baxalta to create the leading global biotechnology company focused on serving people with rare diseases and other highly specialized conditions. While closing this transformative deal and making significant progress on integration, we have delivered strong double-digit revenue growth from our legacy Shire franchises, and for the first time our results reflect a significant contribution from the legacy Baxalta franchises – allowing us to upgrade our guidance for full year 2016.

“In addition, we have advanced key assets in development and have a robust, innovative clinical pipeline with approximately 40 programs focused on areas of significant unmet medical need. We were pleased to receive approval from the FDA for XIIDRA, the first FDA-approved treatment for the signs and symptoms of dry eye disease and the first product in our developing franchise in ophthalmics. We also received a positive CHMP opinion for ONIVYDE, and completed the decentralized procedure to support European approval of CUVITRU, expanding therapeutic options within our Immunology portfolio. Lastly, we are on track for an FDA resubmission for SHP465 later this year to strengthen our ADHD product offerings.

“Baxalta integration activities continue to progress very well and, with our new operating structure in place, we are raising our operating cost synergy expectations by 40% to at least \$700 million in year three post close. This would not have been possible without the commitment of all our employees, who have worked tirelessly in recent months to help drive efficiencies across the business, so that we can continue to deliver best-in-class therapies to patients around the world. We remain resolutely focused on achieving our goals, and I am very confident that Shire will continue to deliver strong growth as we integrate Baxalta and advance our combined portfolio of products.”

## FINANCIAL SUMMARY

### Second Quarter 2016 Unaudited Results

- Total product sales were up 57% versus Q2 2015 (up 58% on a Non GAAP CER basis) at \$2,322 million (Q2 2015: \$1,476 million), primarily due to the inclusion of \$559 million of legacy Baxalta sales, representing 38 percentage points of the reported product sales growth.

Excluding Baxalta, product sales increased 19% (20% on a Non GAAP CER basis) with all legacy Shire franchises exhibiting strong growth in Q2 2016 with Neuroscience up 23%, Genetic Diseases up 16% and Internal Medicine up 19% compared to Q2 2015.

- Royalties and other revenues were up 31% to \$107 million, as Q2 2016 benefited from additional revenue streams acquired with Baxalta primarily related to contract manufacturing activities.
- On a US GAAP basis, operating income was down 27% to \$96 million (Q2 2015: \$133 million), primarily due to higher integration and acquisition costs, amortization of inventory fair value step up and amortization of acquired intangible assets, partially offset by lower in-process R&D (“IPR&D”) impairment charges. Non GAAP operating income increased 58% to \$972 million (Q2 2015: \$614 million), primarily due to the inclusion of Baxalta operating income and higher revenue from legacy Shire products.

Non GAAP EBITDA margin (excluding royalties and other revenue, and cost of sales related to contract manufacturing revenues) was up to 40%, due to product sales growing at a higher rate than total Non GAAP operating expenses.

Research and Development (“R&D”) expenses decreased by 62% compared to Q2 2015, primarily due to lower IPR&D impairment charges in Q2 2016, offset by the inclusion of Baxalta and Dyax operating costs. Non GAAP R&D increased by 18%, primarily due to the inclusion of Baxalta and Dyax R&D costs.

Selling, General and Administrative (“SG&A”) expenses increased by 36%, primarily due to the inclusion of Baxalta and Dyax operating costs and XIIDRA launch preparations. Non GAAP SG&A increased by 43% in Q2 2016.

- On a US GAAP basis, diluted losses per American Depositary Share (“ADS”) were \$0.71 compared to earnings per ADS of \$0.81 in Q2 2015. The Q2 2016 loss was primarily due to lower US GAAP operating income which was reduced by higher integration and acquisition charges, amortization of inventory fair value step up and amortization of acquired intangible assets, all primarily related to the Baxalta transaction. In addition, the Q2 2016 loss included as part of discontinued operations an accrual for a proposed legal settlement related to the divested Dermagraft business.

Non GAAP diluted earnings per ADS increased 29% to \$3.38 (Q2 2015: \$2.63), primarily due to higher Non GAAP operating income, partially offset by the impact of a higher number of shares issued as consideration for the Baxalta transaction.

- On a US GAAP basis, net cash provided by operating activities was up 31% to \$591 million (Q2 2015: \$452 million), primarily due to strong cash receipts from higher sales and the timing of payments of accounts payable and other accruals, partially offset by higher tax and interest payments.

Non GAAP cash generation was up 69% to \$853 million compared to \$505 million in Q2 2015, primarily due to strong cash receipts from higher sales and the timing of payments of accounts payable and other accruals.

Non GAAP free cash flow was up 7% to \$464 million (Q2 2015: \$432 million), less than the growth rate of US GAAP net cash provided by operating activities, primarily due to an increase in capital expenditures of \$107 million in support of manufacturing operations at both legacy Shire and Baxalta.

- Non GAAP net debt at June 30, 2016 was \$23,678 million (December 31, 2015: \$1,459 million) representing long and short term borrowings of \$24,027 million, primarily used to fund the acquisitions of Baxalta and Dyax, other debt primarily related to capital leases of \$344 million and cash and cash equivalents of \$693 million.

## OUTLOOK

Following the strong performance in the first half of the year, we are updating our guidance for 2016.

The guidance provided is for full year 2016 incorporating the legacy Baxalta business as of June 3, 2016. The guidance incorporates expected operating cost synergy savings for 2016 based on our updated target of at least \$700 million in year three post close.

The diluted earnings per ADS forecast assumes a weighted average number of 778 million fully diluted ordinary shares outstanding for 2016 following the equity issuance for the Baxalta transaction.

Full Year 2016	US GAAP Outlook	Non GAAP Outlook <sup>(1)</sup>
Total product sales	\$10.8 - \$11 billion	\$10.8 - \$11 billion
Royalties & other revenues	\$490 - \$530 million	\$490 - \$530 million
Gross margin	58% - 60%	77% - 79%
Combined R&D and SG&A	\$4.2 - \$4.5 billion	\$4.1 - \$4.4 billion
Net interest/other	\$500 - \$550 million	\$400 - \$450 million
Effective tax rate	246% - 462% <sup>(2)</sup>	16% - 18%
Diluted earnings per ADS <sup>(3)</sup>	(\$0.40) - \$0.00	\$12.70 - \$13.10

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

<sup>(2)</sup> For 2016, we expect our effective tax benefit rate on GAAP pre-tax profits from operations to be in the range of 246% - 462%. The GAAP effective tax for 2016 is highly sensitive to the relative quantum of profit before tax, leading to the wide range of the expected GAAP effective tax rate.

<sup>(3)</sup> See page 24 for a reconciliation between US GAAP diluted earnings per ADS and Non GAAP diluted earnings per ADS.

## RECENT DEVELOPMENTS

### Business Developments

#### Combination with Baxalta

- On June 3, 2016, Shire announced that it completed its combination with Baxalta, creating the leading global biotechnology company focused on serving people with rare diseases and other highly specialized conditions.

#### Shire to License SHP647 (formerly known as PF-00547659)

- On June 14, 2016, Shire announced it agreed to license global rights to all indications for SHP647 from Pfizer Inc. The transaction closed on July 1, 2016. SHP647 is an investigational biologic being evaluated for the treatment of moderate-to-severe IBD. SHP647 has been evaluated in more than 700 patients in Phase 1 and 2 trials, and Phase 3 trials are expected to begin after consultation with global regulatory authorities.

### Products

#### ONIVYDE for the treatment of metastatic pancreatic cancer

- On July 25, 2016, Shire announced that the CHMP adopted a positive opinion recommending the marketing authorization for the use of ONIVYDE (irinotecan pegylated liposomal formulation) also known as nal-IRI or MM-398, for the treatment of metastatic adenocarcinoma of the pancreas, in combination with 5-fluorouracil and leucovorin, in adult patients who have progressed following gemcitabine-based therapy.
- The positive opinion from CHMP will be submitted to the European Commission (“EC”), which is responsible for granting marketing authorizations for medicines in the European Union (“EU”). We anticipate a final decision later this year.

#### HYQVIA for the treatment of primary and certain secondary immunodeficiencies

- On July 21, 2016, Shire announced it is launching a pediatric indication for HYQVIA (human normal immunoglobulin (10%), recombinant human hyaluronidase) across the EU. This follows the recent marketing authorization granted by the EC to Baxalta in June 2016.

#### XIIDRA for the treatment of Dry Eye Disease

- On July 11, 2016, Shire announced that the United States Food and Drug Administration (“FDA”) approved XIIDRA (lifitegrast ophthalmic solution) 5%, a twice-daily eye drop solution indicated for the treatment of the signs and symptoms of dry eye disease in adult patients. XIIDRA is the only prescription eye drop indicated for the treatment of both signs and symptoms of this condition. Shire expects to launch XIIDRA in the United States in Q3 2016.

#### REVESTIVE for the treatment of Short Bowel Syndrome (“SBS”)

- On July 7, 2016, Shire announced that the EC granted extension of Market Authorization for REVESTIVE for the treatment of patients aged one year and above with SBS.

#### GLASSIA for the treatment of emphysema due to severe alpha-1 antitrypsin (“AAT”) deficiency

- On June 15, 2016, Shire and Kamada Ltd. announced that the FDA approved an expanded label for GLASSIA, marking the first treatment for adult patients with emphysema due to severe AAT deficiency that can be self-infused at home.

## Pipeline

SHP626 for the treatment of Nonalcoholic Steatohepatitis (“NASH”) with liver fibrosis

- On July 29, 2016, Shire was notified that the FDA granted Fast Track Designation for SHP626 (volixibat) for the treatment of NASH with liver fibrosis. NASH with liver fibrosis is a serious condition with no approved therapies.

SHP607 for the prevention of certain complications of prematurity

- On June 30, 2016, Shire announced that top-line SHP607 study results in premature infants showed no impact on the primary endpoint of reducing the severity of retinopathy of prematurity.
- However, top-line analysis of secondary endpoints showed clinically relevant effects on severe complications related to lung and brain damage. These data support further development of SHP607 in preterm infants; Shire plans to meet with regulatory authorities to discuss the clinical path forward for the program focusing on several complications of prematurity.

SHP465 for the treatment of Attention Deficit Hyperactivity Disorder (“ADHD”)

- On June 29, 2016, Shire announced positive topline results of the SHP465 efficacy and safety study in adults with ADHD. This puts Shire on track to file a Class 2 Resubmission of the New Drug Application (“NDA”) for SHP465 with the FDA by the end of 2016.

SHP625 for the treatment of cholestatic liver disease

- On June 13, 2016, Shire announced that the FDA has granted Breakthrough Therapy Designation for SHP625 (maralixibat) for progressive familial intrahepatic cholestasis type 2.

SHP621 for the treatment of eosinophilic esophagitis (“EoE”)

- On June 13, 2016, Shire announced that the FDA has granted Breakthrough Therapy Designation for SHP621 (budesonide oral suspension) for EoE.

CUVITRU for the treatment of primary immunodeficiency disorders

- On June 10, 2016, Shire announced the successful completion of a decentralized procedure to support approval by 17 authorities in Europe for CUVITRU (IG 20mg/ml solution for subcutaneous injection), a treatment for pediatric and adult patients with primary and certain secondary immunodeficiency disorders, in which part of the body's immune system is missing or does not function properly.

## Legal Proceedings

### Investigation related to DERMAGRAFT

- The Department of Justice (“DOJ”), including the U.S. Attorney’s Office for the Middle District of Florida, Tampa Division and the U.S. Attorney’s Office for Washington, DC, is conducting civil and criminal investigations into the sales and marketing practices of Advanced BioHealing Inc. (“ABH”) relating to Dermagraft in June 2011. Following the disposal of the Dermagraft business in January 2014, Shire retained certain legacy liabilities including any liability that may arise from this investigation.
- Over the last several years, Shire has been cooperating fully with these investigations. As part of its efforts to cooperate, Shire has engaged in discussions with the DOJ about a possible resolution. As part of those discussions, Shire has reached an agreement on a proposal for a civil settlement in the amount of \$350 million plus interest, subject to negotiating a final settlement agreement and obtaining final approvals. Assuming the agreement is finalized, it will resolve the civil investigations conducted by the DOJ, including multiple U.S. Attorney’s Offices and relevant federal and state agencies. The tentative settlement proposal would settle the federal government’s claims under the federal False Claims Act and the Dermagraft Medicaid-related claims for states that opt into the settlement. Some states with Dermagraft Medicaid-related claims might elect to opt out of any final settlement, and those states’ claims would remain unresolved. Material issues remain open and subject to further negotiation and approval by Shire, the DOJ and other relevant federal and state agencies before the tentative settlement can be finalized.

## Board Changes

On June 3, 2016, Shire announced that the appointment of Gail D. Fosler and Albert P.L. Stroucken to the Shire Board of Directors, as previously announced on April 18, 2016, is effective.

## Dividend

In respect of the six months ended June 30, 2016, the Board resolved to pay an interim dividend of 4.63 U.S. cents per Ordinary Share (2015: 4.21 U.S. cents per Ordinary Share).

Dividend payments will be made in Pounds Sterling to holders of Ordinary Shares and in U.S. Dollars to holders of ADSs. A dividend of 3.51<sup>(1)</sup> pence per Ordinary Share (an increase of 30% compared to 2015: 2.69 pence) and 13.89 U.S. cents per ADS (an increase of 10% compared to 2015: 12.63 U.S. cents) will be paid on October 7, 2016 to shareholders on the register as at the close of business on September 9, 2016.

<sup>(1)</sup> Translated using a GBP:USD exchange rate of 1.3202.

## ADDITIONAL INFORMATION

The following additional information is included in this press release:

	<b>Page</b>
Overview of Second Quarter 2016 Financial Results	9
Financial Information	14
Non GAAP Reconciliation	22
Notes to Editors	24
Forward-Looking Statements	25
Non GAAP Measures	27
Trademarks	28

### For further information please contact:

#### Investor Relations

- Sarah Elton-Farr	seltonfarr@shire.com	+44 1256 894157
- Robert Coates	rcoates@shire.com	+44 1256 894874
- Ian Karp	ikarp@shire.com	+1 781 482 9018

#### Media

- Gwen Fisher	gfisher@shire.com	+1 781 482 9649
- Debbi Ford	debbi.ford@shire.com	+1 617 949 9083

Dial in details for the **live conference call** for investors at 14:00 BST / 09:00 EDT on August 2, 2016:

UK dial in:	0808 237 0030 or 020 3139 4830
US dial in:	1 866 928 7517 or 1 718 873 9077
International Access Numbers:	<a href="#">Click here</a>
Password/Conf ID:	78225871#
Live Webcast:	<a href="#">Click here</a>

The quarterly earnings presentation will be available today at 13:00 BST / 08:00 EDT on:

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

## OVERVIEW OF SECOND QUARTER 2016 FINANCIAL RESULTS

### 1. Product sales

For the three months ended Q2 2016, product sales were up 57% to \$2,322 million (Q2 2015: \$1,476 million), primarily due to the inclusion of product sales acquired with Baxalta. Excluding Baxalta, product sales were up 19% (up 20% on a Non GAAP CER basis).

<i>(in millions)</i>				Total Sales	
				Year on year growth	
Product sales	U.S. Sales	International Sales	Total Sales	Reported	Non GAAP CER
CINRYZE	\$ 163.5	\$ 9.5	\$ 173.0	+25%	+25%
ELAPRASE	38.2	115.8	154.0	+5%	+8%
FIRAZYR	119.5	17.2	136.7	+31%	+31%
REPLAGAL	-	118.4	118.4	+1%	+1%
VPRIV	38.5	49.5	88.0	+4%	+4%
KALBITOR	17.7	-	17.7	N/A	N/A
<b>Genetic Diseases total</b>	<b>377.4</b>	<b>310.4</b>	<b>687.8</b>	+16%	+17%
VYVANSE	467.4	50.3	517.7	+22%	+22%
ADDERALL XR	96.1	5.7	101.8	+18%	+18%
Other Neuroscience	14.3	21.4	35.7	+63%	+64%
<b>Neuroscience total</b>	<b>577.8</b>	<b>77.4</b>	<b>655.2</b>	+23%	+23%
LIALDA/MEZAVANT	174.5	19.2	193.7	+23%	+23%
PENTASA	72.9	-	72.9	+10%	+10%
GATTEX/REVESTIVE	36.9	7.6	44.5	+19%	+19%
NATPARA	19.9	-	19.9	+237%	+237%
Other Internal Medicine	35.0	53.7	88.7	+4%	+4%
<b>Internal Medicine total</b>	<b>339.2</b>	<b>80.5</b>	<b>419.7</b>	+19%	+19%
HEMOPHILIA	127.2	148.4	275.6	N/A	N/A
INHIBITOR THERAPIES	28.9	45.1	74.0	N/A	N/A
<b>Hematology total</b>	<b>156.1</b>	<b>193.5</b>	<b>349.6</b>	N/A	N/A
IMMUNOGLOBULIN THERAPIES	104.1	34.1	138.2	N/A	N/A
BIO THERAPEUTICS	22.7	28.6	51.3	N/A	N/A
<b>Immunology total</b>	<b>126.8</b>	<b>62.7</b>	<b>189.5</b>	N/A	N/A
<b>Oncology total</b>	<b>16.2</b>	<b>4.1</b>	<b>20.3</b>	N/A	N/A
<b>Total product sales</b>	<b>\$ 1,593.5</b>	<b>\$ 728.6</b>	<b>\$ 2,322.1</b>	+57%	+58%

#### Genetic Diseases

Genetic Diseases product sales in Q2 2016 increased 16% (up 17% on a Non GAAP CER basis) compared to Q2 2015.

The increase was primarily driven by increased demand for our Hereditary Angioedema therapies, CINRYZE and FIRAZYR, which were up 25% and 31%, respectively, in Q2 2016 compared to Q2 2015. Both products benefitted from strong growth in the number of patients on therapy, higher utilization per patient in Q2 2016 and the impact of pricing actions taken since Q2 2015.

#### Neuroscience

Neuroscience product sales increased 23% in Q2 2016 compared to Q2 2015 with growth primarily driven by VYVANSE.

VYVANSE sales increased 22% due to year-over-year prescription growth in the U.S., the benefit of price increases taken since Q2 2015 and, to a lesser extent, growth in our international markets.

ADDERALL XR sales increased 18% due to increased prescription demand and lower sales deductions as a percentage of product sales in Q2 2016 compared to Q2 2015; partially offset by destocking in Q2 2016 versus stocking in Q2 2015.

### Internal Medicine

Internal Medicine product sales were up 19%, primarily due to continued growth in our gastro-intestinal products.

LIALDA/MEZAVANT sales were up 23% due to an 11% increase in prescription demand, resulting in a market share of 39% at the end of Q2 2016, the impact of a price increase taken since Q2 2015, and to a lesser extent, the impact of stocking in Q2 2016 versus destocking in Q2 2015.

GATTEX/REVESTIVE and NATPARA, which were acquired with NPS Pharmaceuticals, Inc. ("NPS") in Q1 2015, continued to perform well with sales up 19% and 237%, respectively. GATTEX/REVESTIVE sales were up due to an increase in the number of patients on therapy, partially offset by Q2 2016 destocking. NATPARA was launched in April 2015.

### Hematology

The Hematology franchise was acquired with Baxalta in June 2016 and includes sales of recombinant and plasma-derived hemophilia products (primarily factor VIII and factor IX) and inhibitor therapies. Reported product sales in Q2 2016 were \$350 million for the one-month period post-acquisition and represent 24 percentage points of Shire's reported product sales growth.

### Immunology

The Immunology franchise was acquired with Baxalta in June 2016 and includes sales of the company's antibody-replacement immunoglobulin and bio therapeutics therapies. Reported product sales in Q2 2016 were \$190 million for the one-month period post-acquisition and represent 13 percentage points of Shire's reported product sales growth.

### Oncology

The Oncology franchise was acquired with Baxalta in June 2016 and represents 1 percentage point of Shire's reported product sales growth. Product sales relate to ONCASPAR which was acquired by Baxalta in July 2015.

### Baxalta pro forma product sales

The following table presents Q2 2016 Baxalta pro forma sales, assuming the Baxalta transaction occurred on April 1, 2015. Growth rates represent the Q2 2016 pro forma sales compared to recast Q2 2015 pro forma sales as previously disclosed by Baxalta following the separation from Baxter.

<i>(in millions)</i>				Pro forma	
				Year on year growth	
<b>Pro forma product sales</b>	U.S. Sales	International Sales	<b>Total Sales</b>	Reported	Non GAAP CER
HEMOPHILIA	\$ 330.7	\$ 389.4	\$ <b>720.1</b>	+6%	+7%
INHIBITOR THERAPIES	78.0	160.4	<b>238.4</b>	+31%	+33%
<b>Hematology total</b>	<b>408.7</b>	<b>549.8</b>	<b>958.5</b>	+12%	+13%
IMMUNOGLOBULIN THERAPIES	334.1	96.7	<b>430.8</b>	+2%	+2%
BIO THERAPEUTICS	69.8	76.5	<b>146.3</b>	+3%	+5%
<b>Immunology total</b>	<b>403.9</b>	<b>173.2</b>	<b>577.1</b>	+2%	+3%
<b>Oncology total</b>	<b>43.5</b>	<b>9.5</b>	<b>53.0</b>	N/A	N/A
<b>Total</b>	<b>\$ 856.1</b>	<b>\$ 732.5</b>	<b>\$ 1,588.6</b>	+12%	+13%

## 2. Royalties and Other Revenues

<i>(in millions)</i>	Revenue	Year on year growth	
		Reported	Non GAAP CER
SENSIPAR Royalties	\$ 35.6	+2%	+2%
3TC and ZEFFIX Royalties	12.1	+15%	+16%
FOSRENOL Royalties	11.4	+6%	-4%
ADDERALL XR Royalties	5.2	-21%	-21%
Other Royalties and Revenues	42.7	+128%	+126%
Total Royalties and Other Revenues	\$ 107.0	+31%	+30%

Royalties and Other Revenues increased 31% in Q2 2016 compared to Q2 2015, primarily due to \$21 million of contract manufacturing revenue acquired with Baxalta.

## 3. Financial details

### Cost of sales

<i>(in millions)</i>	Q2 2016	% of product sales	Q2 2015	% of product sales
Cost of sales (US GAAP)	\$ 778.1		\$ 228.0	
Cost of contract manufacturing revenue	(17.2)		-	
Cost of product sales	760.9	33%	228.0	15%
Amortization of inventory fair value step-up	(280.7)		(5.1)	
Costs of employee retention awards following AbbVie Inc.'s ("AbbVie") terminated offer	-		(2.7)	
Depreciation	(22.4)		(13.1)	
Non GAAP cost of product sales	\$ 457.8	20%	\$ 207.1	14%

US GAAP cost of product sales as a percentage of product sales increased in Q2 2016 primarily due to the impact of higher amortization of inventory fair value step-ups in 2016 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 product sales as a percentage of product sales increased to 20% in Q2 2016, primarily due to the impact of lower margin product franchises acquired with Baxalta.

### R&D

<i>(in millions)</i>	Q2 2016	% of product sales	Q2 2015	% of product sales
R&D (US GAAP)	\$ 294.8	13%	\$ 775.9	53%
Impairment of IPR&D intangible assets	(8.9)		(523.3)	
Costs of employee retention awards following AbbVie's terminated offer	-		(5.7)	
Depreciation	(5.8)		(8.9)	
Non GAAP R&D	\$ 280.1	12%	\$ 238.0	16%

US GAAP R&D decreased by \$481 million, or 62%, primarily due to IPR&D impairment charges of \$523 million recorded in Q2 2015 related to the SHP625 and SHP608 intangible assets.

Non GAAP R&D increased by \$42 million, or 18%, in Q2 2016, primarily due to the inclusion of Baxalta and Dyax costs. Excluding Baxalta and Dyax costs, Non GAAP R&D decreased 12% in Q2 2016 compared to Q2 2015, primarily due to cost savings from the completion or discontinuation of certain R&D programs since Q2 2015.

**SG&A**

<i>(in millions)</i>	<b>Q2 2016</b>	<b>% of product sales</b>	<b>Q2 2015</b>	<b>% of product sales</b>
SG&A (US GAAP) <sup>(1)</sup>	<b>\$ 675.3</b>	<b>29%</b>	\$ 496.0	34%
Legal and litigation costs	<b>(1.6)</b>		(1.9)	
Costs incurred in connection with AbbVie's terminated offer	-		(17.5)	
Depreciation	<b>(19.7)</b>		(17.9)	
Non GAAP SG&A	<b>\$ 654.0</b>	<b>28%</b>	\$ 458.7	31%

US GAAP SG&A increased by \$179 million, or 36%, primarily due to the inclusion of Baxalta related costs.

Non GAAP SG&A increased by \$195 million, or 43% compared to Q2 2015. Excluding Baxalta related costs, Non GAAP SG&A was up 16% to \$531 million, primarily due to XIIDRA launch preparations.

<sup>(1)</sup> Reported SG&A for periods prior to Q2 2016 have been recast to exclude amortization of acquired intangible assets, which is now presented as a separate line item in the Unaudited Consolidated Statements of Income.

**Integration and acquisition costs**

In Q2 2016, Shire recorded integration and acquisition costs of \$363 million, integration and acquisition costs related to the Baxalta and Dyax transactions were \$417 million, and were partially offset by a net credit of \$58 million for the change in fair value of contingent consideration liabilities.

In Q2 2015, Shire recorded a net credit for integration and acquisition costs of \$212 million, which comprised integration and acquisition costs primarily related to NPS of \$46 million and a net credit of \$258 million for the change in fair value of contingent consideration liabilities primarily relating to SHP625 and SHP608.

**Amortization of acquired intangible assets**

In Q2 2016, Shire recorded amortization of acquired intangible assets of \$213 million (Q2 2015: \$131 million). The increase primarily relates to amortization on the intangible assets acquired with the Baxalta and Dyax transactions.

**Reorganization costs**

In Q2 2016, Shire recorded reorganization costs of \$11 million, primarily related to the planned closure of the Basingstoke, U.K. office and the relocation of roles from Pennsylvania to Massachusetts.

In Q2 2015, Shire recorded reorganization costs of \$13 million, primarily related to the relocation of roles from Pennsylvania to Massachusetts.

**Other expense, net**

<i>(in millions)</i>	<b>Q2 2016</b>	<b>Q2 2015</b>
Other expense, net (US GAAP)	<b>\$ 79.6</b>	\$ 12.7
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	<b>(25.9)</b>	-
Gain on sale of long term investments	-	3.7
Non GAAP Other expense, net	<b>\$ 53.7</b>	\$ 16.4

US GAAP Other expense, net increased \$67 million, primarily due to higher interest expense and amortization of one-time borrowing costs incurred on borrowings used to fund the Baxalta and Dyax transactions.

Non GAAP Other expense, net increased \$37 million, primarily due to higher interest expense as noted above.

**Taxation***(in millions)*

	<u>Q2 2016</u>	<u>Effective tax rate</u>	<u>Q2 2015</u>	<u>Effective tax rate</u>
Income tax benefit (US GAAP)	\$ 70.9	(427%)	\$ 44.1	(37%)
Tax effect of adjustments	(215.8)		(121.5)	
Non GAAP Income tax charge	\$ (144.9)	16%	\$ (77.4)	13%

The effective tax rate on US GAAP income in Q2 2016 was -427% (Q2 2015: -37%) and on a Non GAAP basis was 16% (Q2 2015: 13%).

The effective tax rate in Q2 2016 on US GAAP income from continuing operations of -427% is negative, primarily due to the combined impact of the relative quantum of the profit before tax for the period by jurisdiction and the reversal of deferred tax liabilities from the Baxalta acquisition, including in higher tax territories, inventory and intangible assets amortization as well as significant acquisition and integration costs.

The Q2 2015 US GAAP tax rate was negative primarily due to the reduction in deferred tax liabilities in relation to the impairment of IPR&D intangible assets, the re-measurement of uncertain tax positions relating to ongoing tax audits and the release of certain valuation allowances all recognized during Q2 2015.

The effective tax rate in Q2 2016 on Non GAAP income from continuing operations is higher than the same period in 2015, primarily due to the benefit of the re-measurement of uncertain tax positions relating to ongoing tax audits and the release of certain valuation allowances in Q2 2015, which were not repeated in Q2 2016.

**Discontinued operations**

The loss from discontinued operations in Q2 2016 was \$249 million, net of tax benefit of \$101 million (Q2 2015: \$5 million, net of tax) primarily related to a proposed legal settlement to resolve the previously disclosed Department of Justice investigation associated with the divested Dermagraft business.

## FINANCIAL INFORMATION

### TABLE OF CONTENTS

	<b>Page</b>
Unaudited US GAAP Consolidated Balance Sheets	15
Unaudited US GAAP Consolidated Statements of Income	16
Unaudited US GAAP Consolidated Statements of Cash Flows	17
Selected Notes to the Unaudited US GAAP Financial Statements	
(1) Earnings per share ("EPS")	20
(2) Analysis of revenues	21
Non GAAP reconciliation	22

## Unaudited US GAAP Consolidated Balance Sheets

(in millions, except par value of shares)

	June 30, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 693.4	\$ 135.5
Restricted cash	20.0	86.0
Accounts receivable, net	2,412.4	1,201.2
Inventories	5,798.7	635.4
Prepaid expenses and other current assets	733.6	197.4
Total current assets	9,658.1	2,255.5
Non-current assets:		
Investments	174.0	50.8
Property, plant and equipment ("PP&E"), net	6,596.3	828.1
Goodwill	12,962.4	4,147.8
Other intangible assets, net	40,890.3	9,173.3
Deferred tax asset	129.6	121.0
Other non-current assets	309.8	33.3
Total assets	70,720.5	16,609.8
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	3,728.1	2,050.6
Short term borrowings	2,715.2	1,511.5
Other current liabilities	411.5	144.0
Total current liabilities	6,854.8	3,706.1
Non-current liabilities:		
Long term borrowings	21,312.1	69.9
Deferred tax liability	10,053.8	2,205.9
Other non-current liabilities	2,736.8	798.8
Total liabilities	40,957.5	6,780.7
Equity:		
Common stock of 5p par value; 1,000 shares authorized; and 906.9 shares issued and outstanding (2015: 1,000 shares authorized; and 601.1 shares issued and outstanding)	81.0	58.9
Additional paid-in capital	24,473.2	4,486.3
Treasury stock: 9.1 shares (2015: 9.7 shares)	(302.3)	(320.6)
Accumulated other comprehensive loss	(385.8)	(183.8)
Retained earnings	5,896.9	5,788.3
Total equity	29,763.0	9,829.1
Total liabilities and equity	\$ 70,720.5	\$ 16,609.8

## Unaudited US GAAP Consolidated Statements of Income

(in millions)

	3 months ended June 30,		6 months ended June 30,	
	2016	2015	2016	2015
Revenues:				
Product sales	\$ 2,322.1	\$ 1,476.2	\$ 3,949.4	\$ 2,899.4
Royalties & other revenues	107.0	81.4	189.0	146.6
Total revenues	<u>2,429.1</u>	<u>1,557.6</u>	<u>4,138.4</u>	<u>3,046.0</u>
Costs and expenses:				
Cost of sales	778.1	228.0	1,026.7	455.8
Research and development	294.8	775.9	511.9	969.6
Selling, general and administrative <sup>(1)</sup>	675.3	496.0	1,150.2	914.3
Integration and acquisition costs	363.0	(212.4)	454.1	(136.7)
Amortization of acquired intangible assets	213.0	131.3	347.6	219.6
Reorganization costs	11.0	13.3	14.3	28.5
Gain on sale of product rights	(2.3)	(7.1)	(6.5)	(12.3)
Total operating expenses	<u>2,332.9</u>	<u>1,425.0</u>	<u>3,498.3</u>	<u>2,438.8</u>
Operating income from continuing operations	96.2	132.6	640.1	607.2
Interest income	1.6	0.6	2.6	2.6
Interest expense	(87.2)	(11.3)	(131.9)	(20.9)
Other income/(expense), net	6.0	(2.0)	(2.5)	2.3
Total other expense, net	<u>(79.6)</u>	<u>(12.7)</u>	<u>(131.8)</u>	<u>(16.0)</u>
Income from continuing operations before income taxes and equity in (losses)/earnings of equity method investees	16.6	119.9	508.3	591.2
Income tax benefit/(charge)	70.9	44.1	(11.2)	(13.3)
Equity in (losses)/earnings of equity method investees, net of taxes	(0.9)	0.1	(1.0)	(0.9)
Income from continuing operations, net of taxes	86.6	164.1	496.1	577.0
Loss from discontinued operations, net of taxes	(248.7)	(4.5)	(239.2)	(7.0)
Net (loss)/income	<u>\$ (162.1)</u>	<u>\$ 159.6</u>	<u>\$ 256.9</u>	<u>\$ 570.0</u>

<sup>(1)</sup> Reported SG&A for periods prior to June 30, 2016 have been recast to exclude amortization of acquired intangible assets, which is now presented as a separate line item.

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

(in millions except per share amounts)

	3 months ended June 30,		6 months ended June 30,	
	2016	2015	2016	2015
<b>(Loss)/earnings per Ordinary Share – basic</b>				
Earnings from continuing operations	\$ 0.12	\$ 0.28	\$ 0.78	\$ 0.98
Loss from discontinued operations	(0.36)	(0.01)	(0.38)	(0.01)
(Loss)/earnings per Ordinary Share – basic	\$ (0.24)	\$ 0.27	\$ 0.40	\$ 0.97
(Loss)/earnings per ADS – basic	\$ (0.71)	\$ 0.81	\$ 1.21	\$ 2.90
<b>(Loss)/earnings per Ordinary Share – diluted</b>				
Earnings from continuing operations	\$ 0.12	\$ 0.28	\$ 0.77	\$ 0.97
Loss from discontinued operations	(0.36)	(0.01)	(0.37)	(0.01)
(Loss)/earnings per Ordinary Share – diluted	\$ (0.24)	\$ 0.27	\$ 0.40	\$ 0.96
(Loss)/earnings per ADS – diluted	\$ (0.71)	\$ 0.81	\$ 1.20	\$ 2.88
<b>Weighted average number of shares:</b>				
Basic	682.8	590.5	637.3	589.8
Diluted	682.8	593.2	640.1	593.0

## Unaudited US GAAP Consolidated Statements of Cash Flows

(in millions)

	3 months ended June 30,		6 months ended June 30,	
	2016	2015	2016	2015
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>				
Net (loss)/income	\$ (162.1)	\$ 159.6	\$ 256.9	\$ 570.0
Adjustments to reconcile net (loss)/income to net cash provided by operating activities:				
Depreciation and amortization	260.9	171.2	429.8	291.8
Share based compensation	176.5	29.0	194.8	44.3
Change in fair value of contingent consideration	(56.4)	(258.1)	(45.0)	(255.7)
Impairment of intangible assets	8.9	523.3	8.9	523.3
Amortization of inventory fair value step-up	280.7	5.1	293.5	16.3
Change in deferred taxes	(319.1)	(96.0)	(329.2)	(79.4)
Other, net	27.0	2.8	32.5	(0.3)
Changes in operating assets and liabilities:				
(Increase)/decrease in accounts receivable	(80.1)	0.2	(181.0)	(84.9)
(Decrease)/increase in sales deduction accrual	(7.2)	61.9	66.4	37.3
Increase in inventory	(84.2)	(15.4)	(116.4)	(37.4)
Decrease/(increase) in prepayments and other assets	48.7	(14.0)	26.5	28.4
Increase/(decrease) in accounts payable and other liabilities	497.3	(117.3)	342.7	(39.8)
Net cash provided by operating activities	<u>590.9</u>	<u>452.3</u>	<u>980.4</u>	<u>1,013.9</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>				
Movements in restricted cash	2.4	(5.0)	67.2	(19.5)
Purchases of subsidiary undertakings and businesses, net of cash acquired	(11,783.4)	(49.5)	(17,476.2)	(5,249.2)
Purchases of non-current investments and PP&E	(127.5)	(22.9)	(179.1)	(44.7)
Proceeds from short-term investments	-	12.5	-	67.0
Proceeds from disposal of non-current investments	-	4.4	-	4.4
Proceeds received on sale of product rights	2.6	4.9	5.6	8.8
Other, net	(4.8)	(1.3)	(2.3)	(0.9)
Net cash used in investing activities	<u>(11,910.7)</u>	<u>(56.9)</u>	<u>(17,584.8)</u>	<u>(5,234.1)</u>

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

(in millions)

	3 months ended June 30,		6 months ended June 30,	
	2016	2015	2016	2015
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>				
Proceeds from revolving line of credit, long term and short term borrowings	<b>12,590.0</b>	695.6	<b>18,895.0</b>	2,925.6
Repayment of revolving line of credit, long term and short term borrowings	<b>(505.2)</b>	(995.7)	<b>(1,500.3)</b>	(1,530.9)
Payment of dividend	<b>(130.2)</b>	(110.2)	<b>(130.2)</b>	(110.2)
Excess tax benefit associated with exercise of stock options	<b>1.9</b>	7.1	<b>5.1</b>	27.0
Debt issuance costs	<b>(18.5)</b>	(0.4)	<b>(112.3)</b>	(3.7)
Contingent consideration payments	<b>(2.1)</b>	(2.1)	<b>(4.2)</b>	(4.5)
Other, net	<b>11.2</b>	(0.9)	<b>11.1</b>	(0.8)
Net cash provided by/(used in) financing activities	<b>11,947.1</b>	(406.6)	<b>17,164.2</b>	1,302.5
Effect of foreign exchange rate changes on cash and cash equivalents	<b>(2.9)</b>	0.9	<b>(1.9)</b>	(0.7)
Net increase/(decrease) in cash and cash equivalents	<b>624.4</b>	(10.3)	<b>557.9</b>	(2,918.4)
Cash and cash equivalents at beginning of period	<b>69.0</b>	74.3	<b>135.5</b>	2,982.4
Cash and cash equivalents at end of period	<b>\$ 693.4</b>	\$ 64.0	<b>\$ 693.4</b>	\$ 64.0

## Selected Notes to the Unaudited US GAAP Financial Statements

### (1) Earnings Per Share (“EPS”) (in millions)

	3 months ended June 30,		6 months ended June 30,	
	2016	2015	2016	2015
Income from continuing operations	\$ 86.6	\$ 164.1	\$ 496.1	\$ 577.0
Loss from discontinued operations	(248.7)	(4.5)	(239.2)	(7.0)
Numerator for EPS	\$ (162.1)	\$ 159.6	\$ 256.9	\$ 570.0
Weighted average number of shares:				
Basic	682.8	590.5	637.3	589.8
Effect of dilutive shares:				
Share based awards to employees	-	2.7	2.8	3.2
Diluted	682.8	593.2	640.1	593.0
The share equivalents not included in the calculation of the diluted weighted average number of shares are shown below:				
Share based awards to employees	8.3	1.0	4.4	3.2

## Selected Notes to the Unaudited US GAAP Financial Statements

### (2) Analysis of revenues (in millions)

	3 months ended June, 30		6 months ended June, 30	
	2016	2015	2016	2015
<b>Product sales:</b>				
CINRYZE	\$ 173.0	\$ 138.8	\$ 337.2	\$ 286.9
ELAPRASE	154.0	146.5	277.6	271.5
FIRAZYR	136.7	104.1	265.0	196.6
REPLAGAL	118.4	116.9	221.6	214.4
VPRIV	88.0	84.7	171.6	171.1
KALBITOR	17.7	-	28.1	-
<b>Genetic Diseases total</b>	<b>687.8</b>	<b>591.0</b>	<b>1,301.1</b>	<b>1,140.5</b>
VYVANSE	517.7	424.8	1,026.9	841.6
ADDERALL XR	101.8	86.0	200.6	181.7
Other Neuroscience	35.7	21.9	57.8	52.4
<b>Neuroscience total</b>	<b>655.2</b>	<b>532.7</b>	<b>1,285.3</b>	<b>1,075.7</b>
LIALDA/MEZAVANT	193.7	157.9	361.7	306.4
PENTASA	72.9	66.3	136.9	145.0
GATTEX/REVESTIVE	44.5	37.3	96.2	52.2
NATPARA	19.9	5.9	35.5	5.9
Other Internal Medicine	88.7	85.1	173.3	173.7
<b>Internal Medicine total</b>	<b>419.7</b>	<b>352.5</b>	<b>803.6</b>	<b>683.2</b>
HEMOPHILIA	275.6	-	275.6	-
INHIBITOR THERAPIES	74.0	-	74.0	-
<b>Hematology total</b>	<b>349.6</b>	<b>-</b>	<b>349.6</b>	<b>-</b>
IMMUNOGLOBULIN THERAPIES	138.2	-	138.2	-
BIO THERAPEUTICS	51.3	-	51.3	-
<b>Immunology total</b>	<b>189.5</b>	<b>-</b>	<b>189.5</b>	<b>-</b>
<b>Oncology total</b>	<b>20.3</b>	<b>-</b>	<b>20.3</b>	<b>-</b>
<b>Total product sales</b>	<b>2,322.1</b>	<b>1,476.2</b>	<b>3,949.4</b>	<b>2,899.4</b>
<b>Royalties and Other Revenues:</b>				
SENSIPAR Royalties	35.6	34.8	73.5	45.2
3TC and ZEFFIX Royalties	12.1	10.5	27.1	18.0
FOSRENOL Royalties	11.4	10.8	20.6	19.2
ADDERALL XR Royalties	5.2	6.6	11.0	15.1
Other Royalties and Revenues	42.7	18.7	56.8	49.1
<b>Total Royalties and Other Revenues</b>	<b>107.0</b>	<b>81.4</b>	<b>189.0</b>	<b>146.6</b>
<b>Total Revenues</b>	<b>\$ 2,429.1</b>	<b>\$ 1,557.6</b>	<b>\$ 4,138.4</b>	<b>\$ 3,046.0</b>

**Non GAAP reconciliation for the three months and six months ended June 30, 2016 and 2015**  
(in millions)

Reconciliation of US GAAP net (loss)/income to Non GAAP EBITDA:

	<u>3 months ended June 30,</u>		<u>6 months ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
<b>US GAAP Net (loss)/income</b>	<b>\$ (162.1)</b>	<b>\$ 159.6</b>	<b>\$ 256.9</b>	<b>\$ 570.0</b>
Add back/(deduct):				
Loss from discontinued operations, net of tax	<b>248.7</b>	4.5	<b>239.2</b>	7.0
Equity in losses/(earnings) of equity method investees, net of taxes	<b>0.9</b>	(0.1)	<b>1.0</b>	0.9
Income tax (benefit)/charge	<b>(70.9)</b>	(44.1)	<b>11.2</b>	13.3
Other expense, net	<b>79.6</b>	12.7	<b>131.8</b>	16.0
 US GAAP Operating income from continuing operations	 <b>96.2</b>	 132.6	 <b>640.1</b>	 607.2
Add back/(deduct) Non GAAP adjustments:				
Acquisition and integration activities	<b>643.7</b>	(207.3)	<b>747.6</b>	(120.4)
Amortization of acquired intangible assets	<b>213.0</b>	131.3	<b>347.6</b>	219.6
Depreciation	<b>47.9</b>	39.9	<b>82.2</b>	72.2
Asset impairments	<b>8.9</b>	523.3	<b>8.9</b>	523.3
Divestments and reorganizations	<b>8.7</b>	6.2	<b>7.8</b>	16.2
Legal and litigation costs	<b>1.6</b>	1.9	<b>16.6</b>	2.7
Other	<b>-</b>	26.0	<b>-</b>	48.0
 <b>Non GAAP EBITDA</b>	 <b>1,020.0</b>	 653.9	 <b>1,850.8</b>	 1,368.8
 Depreciation	 (47.9)	 (39.9)	 (82.2)	 (72.2)
 <b>Non GAAP Operating income from continuing operations</b>	 <b>\$ 972.1</b>	 <b>\$ 614.0</b>	 <b>\$ 1,768.6</b>	 <b>\$ 1,296.6</b>
 <b>Net income margin</b> <sup>(1)</sup>	 <b>(7%)</b>	 10%	 <b>6%</b>	 19%
 <b>Non GAAP EBITDA margin</b> <sup>(2)</sup>	 <b>40%</b>	 39%	 <b>43%</b>	 42%

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

<sup>(2)</sup> Non GAAP EBITDA as a percentage of product sales, excluding royalties and other revenues, and cost of contract manufacturing revenues.

Reconciliation of US GAAP product sales to Non GAAP Gross Margin:

	<u>3 months ended June 30,</u>		<u>6 months ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
<b>US GAAP Product Sales</b>	<b>\$ 2,322.1</b>	<b>\$ 1,476.2</b>	<b>\$ 3,949.4</b>	<b>\$ 2,899.4</b>
(Deduct)/add back:				
Cost of sales (US GAAP)	<b>(778.1)</b>	(228.0)	<b>(1,026.7)</b>	(455.8)
Cost of contract manufacturing revenue	<b>17.2</b>	-	<b>17.2</b>	-
Amortization of inventory fair value step-up	<b>280.7</b>	5.1	<b>293.6</b>	16.3
Costs of employee retention awards following AbbVie's terminated offer	<b>-</b>	2.8	<b>-</b>	5.5
Depreciation	<b>22.4</b>	13.1	<b>30.7</b>	24.8
<b>Non GAAP Gross Margin</b>	<b>\$ 1,864.4</b>	<b>\$ 1,269.2</b>	<b>\$ 3,264.3</b>	<b>\$ 2,490.2</b>
<b>Non GAAP Gross Margin %</b> <sup>(1)</sup>	<b>80.3%</b>	86.0%	<b>82.7%</b>	85.9%

<sup>(1)</sup> Non GAAP Gross Margin as a percentage of product sales.

## Non GAAP reconciliation for the three months and six months ended June 30, 2016 and 2015

(in millions except per ADS amounts)

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

	3 months ended June 30,		6 months ended June 30,	
	2016	2015	2016	2015
<b>US GAAP diluted earnings per ADS</b>	\$ (0.71)	\$ 0.81	\$ 1.20	\$ 2.88
Amortization and asset impairments	0.72	2.79	1.22	3.07
Acquisition and integration costs	2.25	(1.08)	2.94	(0.71)
Divestments, reorganizations and discontinued operations	1.12	0.02	1.17	0.07
Legal and litigation costs	-	0.01	0.05	0.01
Other Non GAAP adjustments	-	0.08	-	0.15
<b>Non GAAP diluted earnings per ADS</b>	<b>\$ 3.38</b>	<b>\$ 2.63</b>	<b>\$ 6.58</b>	<b>\$ 5.47</b>

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

	3 months ended June 30,		6 months ended June 30,	
	2016	2015	2016	2015
<b>Net cash provided by operating activities</b>	\$ 590.9	\$ 452.3	\$ 980.4	\$ 1,013.9
Tax and interest payments, net	262.3	53.0	365.1	7.2
<b>Non GAAP cash generation</b>	<b>\$ 853.2</b>	<b>\$ 505.3</b>	<b>\$ 1,345.5</b>	<b>\$ 1,021.1</b>

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

	3 months ended June 30,		6 months ended June 30,	
	2016	2015	2016	2015
<b>Net cash provided by operating activities</b>	\$ 590.9	\$ 452.3	\$ 980.4	\$ 1,013.9
Capital expenditure	(127.1)	(20.5)	(178.8)	(39.8)
<b>Non GAAP free cash flow</b>	<b>\$ 463.8</b>	<b>\$ 431.8</b>	<b>\$ 801.6</b>	<b>\$ 974.1</b>

Non GAAP net debt comprises:

	June 30, 2016	December 31, 2015
Cash and cash equivalents	\$ 693.4	\$ 135.5
Long term borrowings	(21,312.1)	(69.9)
Short term borrowings	(2,715.2)	(1,511.5)
Other debt	(343.6)	(13.4)
<b>Non GAAP net debt</b>	<b>\$ (23,677.5)</b>	<b>\$ (1,459.3)</b>

Reconciliation of full year 2016 US GAAP diluted earnings per ADS Outlook to Non GAAP diluted earnings per ADS Outlook:

	Full Year 2016 Outlook	
	Min	Max
<b>US GAAP diluted earnings per ADS</b>	\$ (0.40)	\$ 0.00
Amortization and asset impairments	3.07	
Acquisition and integration costs	8.89	
Divestments, reorganizations and discontinued operations	1.07	
Legal and litigation costs	0.07	
<b>Non GAAP diluted earnings per ADS</b>	<b>\$ 12.70</b>	<b>\$ 13.10</b>

## **NOTES TO EDITORS**

Stephen Williams, Deputy Company Secretary (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 and other highly specialized conditions. 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](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 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 combined 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 with respect to Shire’s acquisition of NPS, Dyax or Baxalta 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 the 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;
- difficulties in integrating Dyax or Baxalta into Shire may lead to the combined company not being able to realize the expected operating efficiencies, cost savings, revenue enhancements, synergies or other benefits at the time anticipated or at all; and

other risks and uncertainties detailed from time to time in Shire's filings with the Securities and Exchange Commission, including those risks outlined in "ITEM 1A: Risk Factors" in Shire's Annual Report on Form 10-K for the year ended December 31, 2015.

All forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Except to the extent otherwise required by applicable law, we do not undertake any obligation to 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 product sales; Non GAAP gross margin; Non GAAP R&D; Non GAAP SG&A; Non GAAP other expense; Non GAAP cash generation; Non GAAP free cash flow, Non GAAP net debt, Non GAAP EBITDA and Non GAAP EBITDA margin* (excluding royalties and other revenues and cost of sales related to contract manufacturing revenues).

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

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

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

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

A reconciliation of Non GAAP financial measures to the most directly comparable measure under US GAAP is presented on pages 22 to 23.

Non GAAP CER growth is computed by restating 2016 results using average 2015 foreign exchange rates for the relevant period.

Average exchange rates used by Shire for Q2 2016 were \$1.45:£1.00 and \$1.13:€1.00 (2015: \$1.52:£1.00 and \$1.10:€1.00). Average exchange rates used by Shire for the six months to June 30, 2016 were \$1.44:£1.00 and \$1.11:€1.00 (2015: \$1.53:£1.00 and \$1.13:€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.