

Press Release



Shire reports strong Q2 2017 operating results and cash flow; updates full year guidance

Q2 product sales growth of 7% on a combined pro forma basis; generated \$1.2 billion operating cash flow

Over-delivered Year 1 Baxalta integration cost synergies, recognizing \$400 million vs \$300 million target

Exploring strategic review of Neuroscience franchise, including potential of independent public listing

Significant pipeline progress with SHP643 (lanadelumab); Phase 3 topline data demonstrates potential to change treatment paradigm for patients with HAE; U.S. approval of MYDAYIS for patients with ADHD; September launch planned

August 3, 2017 – Shire plc (Shire) (LSE: SHP, NASDAQ: SHPG) announces unaudited results for the three months ended June 30, 2017.

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

“During the second quarter, we delivered strong top-line growth of 7% on a pro forma basis, generating product sales of \$3.6 billion. Our Immunology franchise grew by 18%, and we saw significant contributions across our broad and diverse portfolio. Shire remains ahead of schedule to deliver at least \$700 million in cost synergies from the Baxalta integration by Year 3. The Q2 performance resulted in strong operating cash flow of \$1.2 billion and enabled us to reduce Non GAAP net debt by \$880 million in the quarter.

“We also continue to drive the late-stage clinical pipeline. In Q2 we announced positive topline data from our Phase 3 pivotal trial of SHP643 in HAE, and anticipate submission of the BLA in late 2017 or early 2018. MYDAYIS, a once-daily treatment for patients with ADHD, received US FDA approval and will be launched in September.

“We are at an exciting inflection point, with both our rare disease and neuroscience businesses performing strongly and each having significant growth potential over the coming years. The strength and scale of our business provides us with the opportunity to further optimize our franchise portfolio - one of our key priorities communicated earlier this year. By year end, we expect to complete a formal evaluation of the full range of strategic options for the neuroscience franchise, including the potential for its independent public listing.

“As we enter the second half of 2017, we are focused on generating strong organic growth while continuing to deliver on our key priorities - launching more than 80 products globally by leveraging our expanded commercial platform, progressing our late-stage pipeline, integrating Baxalta, and paying down debt. We have updated our 2017 full year guidance and remain very confident about Shire’s long-term prospects.”

Financial Highlights

	Q2 2017 ⁽¹⁾	Growth ⁽¹⁾	Non GAAP CER ⁽¹⁾⁽²⁾
Product sales	\$3,592 million	+55%	+56%
Product sales excluding legacy Baxalta	\$1,882 million	+7%	
Total revenues	\$3,746 million	+54%	+56%
Operating income from continuing operations	\$399 million	+315%	
Non GAAP operating income ⁽²⁾	\$1,492 million	+53%	+54%
Net income margin ⁽³⁾⁽⁴⁾	6%	13ppc	
Non GAAP EBITDA margin ⁽²⁾⁽⁴⁾	43%	1ppc	
Net income	\$240 million	N/M	
Non GAAP net income ⁽²⁾	\$1,135 million	+47%	
Diluted earnings per ADS ⁽⁵⁾	\$0.79	N/M	
Non GAAP diluted earnings per ADS ⁽²⁾⁽⁵⁾	\$3.73	+10%	+11%
Net cash provided by operating activities	\$1,223 million	+107%	
Non GAAP free cash flow ⁽²⁾	\$1,064 million	+130%	

⁽¹⁾ Results include Baxalta Inc. (Baxalta) (acquired on June 3, 2016), unless otherwise noted. Percentages compare to equivalent 2016 period. ⁽²⁾ The Non GAAP financial measures included within this release are explained on pages 28 – 29, and are reconciled to the most directly comparable financial measures prepared in accordance with US GAAP on pages 22 – 24. ⁽³⁾ US GAAP net income as a percentage of total revenues. ⁽⁴⁾ Percentage point change (ppc). ⁽⁵⁾ Diluted weighted average number of ordinary shares 913 million.

Product sales growth

- Delivered product sales growth of 55% with the inclusion of legacy Baxalta sales.
- Achieved combined pro forma product sales growth of 7%; legacy Shire product sales growth of 7% and legacy Baxalta pro forma product sales growth of 8%.
- Strong demand for our immunology products delivered 18% pro forma sales growth, with significant contributions from our subcutaneous immunoglobulin portfolio as well as GAMMAGARD LIQUID and our albumin products.

Earnings growth

- Generated Non GAAP earnings per ADS of \$3.73, underscoring continued focus on commercial excellence and operating efficiency.
- Continued to progress Baxalta integration, while delivering \$400 million in cost synergies in year 1 - exceeding our target of \$300 million - which contributed to a Non GAAP EBITDA margin of 43% for the quarter; on-track to achieve at least \$700 million in synergies by year 3.

Strong cash flow

- Strong operating cash flow enabled \$880 million reduction in Non GAAP net debt since March 31, 2017; remain on-track to achieve our year-end debt target.

Product and Pipeline Highlights

Regulatory updates

- Received U.S. Food and Drug Administration (FDA) approval of MYDAYIS, a new once-daily treatment option for symptom control in Attention Deficit Hyperactivity Disorder (ADHD) patients 13 years and older.
- Granted European Union (EU) Conditional Marketing Authorization for NATPAR (Parathyroid Hormone) for the treatment of patients with Chronic Hypoparathyroidism.
- Received European Medicines Agency (EMA) validation of VEYVONDI [von Willebrand factor (Recombinant)] Marketing Authorization Application for treatment of von Willebrand Disease (VWD).
- Submitted Investigational New Drug (IND) application to FDA for gene therapy candidate SHP654 for the treatment of hemophilia A.

Clinical and business development updates

- Reported positive topline data for SHP643 (lanadelumab), which was acquired with Dyax Corp. (Dyax), an investigational treatment that reduced Hereditary Angioedema (HAE) monthly attack rate by 87% versus placebo in a Phase 3 26-week pivotal trial.
- Entered into an agreement with Parion Sciences to develop and commercialize SHP659 (formerly known as P-321), an investigational epithelial sodium channel (ENaC) inhibitor for the potential treatment of Dry Eye Disease in adults.
- Expanded broad antibody research platform through license agreement with Novimmune S.A. to develop and commercialize an innovative, differentiated bi-specific antibody in pre-clinical development for the treatment of hemophilia A and hemophilia A patients with inhibitors.

FINANCIAL SUMMARY - SECOND QUARTER 2017 COMPARED TO SECOND QUARTER 2016

Revenues

- Product sales increased 55% to \$3,592 million (Q2 2016: \$2,322 million), primarily due to the inclusion of a full quarter of legacy Baxalta sales of \$1,710 million in Q2 2017.
- Product sales excluding legacy Baxalta increased 7% primarily due to growth from our Internal Medicine franchise, up 15%, as well as sales from our Ophthalmology franchise of \$57 million.
- Royalties and other revenues increased 44% to \$154 million, as Q2 2017 benefited from a full quarter of additional revenue acquired with Baxalta, primarily related to contract manufacturing activities.

Operating results

- Operating income increased 315% to \$399 million (Q2 2016: \$96 million), primarily due to the inclusion of a full quarter of Baxalta operating income and higher revenue from our Internal Medicine franchise, partially offset by higher amortization of acquired intangible assets and higher costs relating to licensing arrangements.
- Non GAAP operating income increased 53% to \$1,492 million (Q2 2016: \$972 million), primarily due to the inclusion of a full quarter of Baxalta operating income and higher revenue from legacy Shire products.
- Non GAAP EBITDA margin as a percentage of total revenues increased to 43% (Q2 2016: 42%), primarily due to lower research and development (R&D) and selling, general and administrative (SG&A) expenditures as a percentage of revenues, partially offset by a lower Non GAAP gross margin, primarily due to the inclusion of a full quarter of lower margin product franchises acquired with Baxalta.

Earnings per share (EPS)

- Diluted earnings per American Depositary Shares (ADS) increased to \$0.79 (Q2 2016: diluted losses per ADS of \$0.71), primarily due to higher operating income due to the inclusion of a full quarter of Baxalta income and the impact of lower losses from discontinued operations related to the divested Dermagraft business.
- Non GAAP diluted earnings per ADS increased 10% to \$3.73 (Q2 2016: \$3.38), as higher Non GAAP operating income more than offset the impact of additional shares issued as consideration for the Baxalta transaction.

Cash flows

- Net cash provided by operating activities increased 107% to \$1,223 million (Q2 2016: \$591 million), primarily due to strong cash receipts from higher sales and operating profitability, partially offset by the timing of payments of accounts payable and other accruals.
- Non GAAP free cash flow increased 130% to \$1,064 million (Q2 2016: \$463 million), driven by the growth in net cash provided by operating activities noted above, partially offset by an increase of \$51 million in capital expenditures, primarily related to our continued investment in manufacturing operations.

Debt

- Non GAAP net debt at June 30, 2017 decreased \$1,143 million since December 31, 2016, to \$21,296 million (December 31, 2016: \$22,439 million). The decrease was primarily due to a \$1,416 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 \$21,209 million, and capital leases of \$351 million, partially offset by cash and cash equivalents of \$264 million.

OUTLOOK

Following the strong performance in the first half of the year, we are updating our guidance for 2017.

The guidance incorporates accelerated synergy capture as well as an updated view on our product sales, primarily due to a new generic LIALDA competitor. We have also revised our depreciation estimate to be \$450 - \$500 million, based on updates resulting from the Baxalta integration, and we have lowered our capital expenditure forecast to \$800 - \$900 million.

Non GAAP EPS has been upgraded by raising the midpoint of our guidance range by 10 cents to \$15.00, driven by cost discipline and accelerated synergy capture.

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

Our US GAAP diluted earnings per ADS outlook has been updated to reflect ongoing integration activities, which has accelerated the recognition of synergies, and the change in fair value of contingent consideration for SHP643 (lanadelumab) resulting from the positive topline Phase 3 results.

Full Year 2017	US GAAP Outlook	Non GAAP Outlook ⁽¹⁾
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 ⁽²⁾	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 ⁽³⁾	\$5.65 - \$6.05	\$14.80 - \$15.20

⁽¹⁾ For a list of items excluded from Non GAAP Outlook, refer to pages 28 - 29 of this release.

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

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

RECENT DEVELOPMENTS

Corporate Strategy

Shire to assess strategic options for its Neuroscience franchise

- With the acquisition and integration of Baxalta, Shire has solidified its leadership position in rare diseases with an unparalleled inline portfolio, innovative pipeline, and global commercial infrastructure. As part of the Board's ongoing commitment to optimize Shire's portfolio and strategic focus, Shire is assessing strategic options for our Neuroscience franchise to derive even greater value from this franchise. These options may include the independent public listing of the Neuroscience franchise. Shire intends to complete this strategic review by year end.

Business Development

Shire enters into a licensing agreement for Novimmune bi-specific antibody

- On July 18, 2017, Shire entered into a licensing agreement with Novimmune S.A. The license grants Shire exclusive worldwide rights to develop and commercialize an innovative, bi-specific antibody in pre-clinical development for the treatment of hemophilia A and hemophilia A patients with inhibitors.

Products

FIRAZYR for the treatment of HAE in Japan

- On July 6, 2017, Shire submitted a Japanese New Drug Application to the Pharmaceutical and Medical Devices Agency in Japan for the treatment of HAE.

VEYVONDI for the treatment of adults affected by VWD

- On June 22, 2017, Shire announced that the EMA validated the Marketing Authorization Application for VEYVONDI to prevent and treat bleeding episodes and peri-operative bleeding in adults (age 18 and older) diagnosed with VWD.

MYDAYIS for the treatment of ADHD

- On June 20, 2017, Shire announced that the FDA has approved MYDAYIS (mixed salts of a single-entity amphetamine product), a once-daily treatment comprised of three different types of drug-releasing beads for patients aged 13 years and older with ADHD.

INTUNIV for the treatment of ADHD in Japan

- On May 29, 2017, Shire's partner in Japan, Shionogi & Co., Ltd, launched INTUNIV for the treatment of ADHD in children and adolescents from 6 to 17 years old.

Pipeline

SHP654 for the treatment of hemophilia A

- On July 6, 2017, Shire announced the submission of an IND application to the FDA for SHP654, an investigational factor VIII (FVIII) gene therapy for the treatment of hemophilia A.

SHP643 for the treatment of HAE

- On May 18, 2017, Shire announced positive topline Phase 3 results for the HELP Study, which evaluated the efficacy and safety of subcutaneously administered lanadelumab in patients 12 years of age or older with HAE. The study met its primary endpoint and all secondary endpoints.

SHP647 for the treatment of ulcerative colitis

- On May 17, 2017, Shire announced the publication of positive Phase 2 results for the TURANDOT Study. The study met its primary endpoint, demonstrating significantly greater remission rates in patients receiving the anti-MAdCAM antibody. Shire continues to work towards the initiation of a pivotal Phase 3 trial for SHP647 in the second half of 2017.

SHP680 for the treatment of multiple neurological conditions

- Shire is advancing clinical development of SHP680, targeting indications for multiple neurological conditions with high unmet need. SHP680 is a new chemical entity prodrug of d-amphetamine, which has previously been studied in Phase 1 clinical trials, demonstrating a unique PK profile. It belongs to a class of molecules with an established and well understood safety profile.

Board Changes

In accordance with Shire's normal succession planning, the Company announces that the following Non-Executive Directors will retire from the Board with effect from the conclusion of the 2018 Annual General Meeting ("AGM"):

- William M. Burns, Senior Independent Director
- David Ginsburg, Chairman of the Science & Technology Committee
- Anne Minto, Chairman of the Remuneration Committee

Al Stroucken, Non-Executive Director, will assume the position of Chairman of the Remuneration Committee effective August 3, 2017. Anne Minto will continue to serve as a member of the Remuneration Committee to enable a period of transition until her retirement from the Board. Anne will fully support Al in the shareholder consultation process ahead of the publication of the new Directors' Remuneration Policy that will be put forward for shareholder approval at the 2018 AGM. The Board, supported by the Nomination & Governance Committee, will continue to evaluate Board and committee membership, including succession plans for the roles of Senior Independent Director and Chairman of the Science & Technology Committee, and will announce further changes once finalized.

Dividend

In respect of the six months ended June 30, 2017, the Board resolved to pay an interim dividend of 5.09 U.S. cents per Ordinary Share (2016: 4.63 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 3.85⁽¹⁾ pence per Ordinary Share (2016: 3.51 pence) and 15.27 U.S. cents per ADS (2016: 13.89 U.S. cents) will be paid on October 20, 2017, to shareholders on the register as of the close of business on September 8, 2017.

Holders of Ordinary Shares are notified that, in order to receive UK sourced dividends via Shire's Income Access Share arrangements ("IAS Arrangements"), they need to have submitted a valid IAS Arrangements election form to the Company's Registrar, Equiniti, by no later than 5pm (BST) on September 22, 2017. Holders of Ordinary Shares are advised that:

- any previous elections made using versions of the IAS Arrangements election form in use prior to February 16, 2016, and any elections deemed to have been made prior to April 28, 2016, are no longer valid; and
- if they do not elect, or have not elected using the newly formatted IAS Arrangements election forms published on or after February 16, 2016, to receive UK sourced dividends via Shire's IAS Arrangements, their dividends will be Irish sourced and therefore incur Irish dividend withholding tax, subject to applicable exemptions.

Internet links to the newly formatted IAS Arrangements election forms can be found at:

<http://investors.shire.com/shareholder-information/shareholder-forms.aspx>

⁽¹⁾ Translated using a GBP:USD exchange rate of 1.3221.

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 August 3, 2017:

UK dial in:	0808 237 0030 or 020 3139 4830
US dial in:	1 866 928 7517 or 1 718 873 9077
International Access Numbers:	Click here
Password/Conf ID:	96350792#
Live Webcast:	Click here

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

- [Shire.com Investors section](#)

- [Shire's IR Briefcase in the iTunes Store](#)

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

1. Product sales

Product sales increased 55% to \$3,592 million (Q2 2016: \$2,322 million), primarily due to the inclusion of a full quarter of legacy Baxalta sales in Q2 2017. Excluding legacy Baxalta, product sales increased 7%.

(in millions)				Total Sales Year on year growth	
				Reported	Non GAAP CER
Product sales by franchise	U.S. Sales	International Sales	Total Sales		
HEMOPHILIA	\$ 383.1	\$ 360.8	\$ 743.9	N/M	N/M
INHIBITOR THERAPIES	76.1	144.6	220.7	N/M	N/M
Hematology total	459.2	505.4	964.6	N/M	N/M
CINRYZE	164.7	11.2	175.9	+2%	+2%
ELAPRASE	39.8	121.2	161.0	+5%	+5%
FIRAZYR	118.1	19.3	137.4	+1%	+1%
REPLAGAL	—	122.1	122.1	+3%	+6%
VPRIV	37.3	50.6	87.9	-0%	+2%
KALBITOR	20.6	—	20.6	+16%	+16%
Genetic Diseases total	380.5	324.4	704.9	+2%	+3%
IMMUNOGLOBULIN THERAPIES	407.9	102.6	510.5	N/M	N/M
BIO THERAPEUTICS	75.9	96.3	172.2	N/M	N/M
Immunology total	483.8	198.9	682.7	N/M	N/M
VYVANSE	460.1	58.1	518.2	+0%	+0%
ADDERALL XR	67.2	4.2	71.4	-30%	-30%
MYDAYIS	15.7	—	15.7	N/A	N/A
Other Neuroscience	5.2	24.9	30.1	-16%	-12%
Neuroscience total	548.2	87.2	635.4	-3%	-2%
LIALDA/MEZAVANT	187.5	20.3	207.8	+7%	+8%
PENTASA	83.3	—	83.3	+14%	+14%
GATTEX/REVESTIVE	63.7	11.6	75.3	+69%	+70%
NATPARA	34.5	—	34.5	+73%	+73%
Other Internal Medicine	31.2	52.2	83.4	-6%	-3%
Internal Medicine total	400.2	84.1	484.3	+15%	+16%
Oncology total	45.8	16.7	62.5	N/M	N/M
Ophthalmology total	57.4	—	57.4	N/A	N/A
Total product sales	\$ 2,375.1	\$ 1,216.7	\$ 3,591.8	+55%	+56%

Hematology

Hematology, acquired with Baxalta in June 2016, reported product sales of \$965 million. Hematology includes sales of recombinant and plasma-derived hemophilia products (primarily factor VIII and factor IX) and inhibitor therapies. Pro forma Q2 2017 growth in Hematology was approximately 1%. U.S. sales growth in Hemophilia, which benefited from stocking in the quarter, was partially offset by overall hematology performance in our international markets due to the timing of large orders.

Genetic Diseases

Genetic Diseases product sales increased 2%. Growth was primarily driven by our lysosomal storage diseases (LSD) portfolio.

ELAPRASE sales increased by 5%, while REPLAGAL sales increased by 3%. Both products benefited from an increase in the number of patients on therapy.

Immunology

Immunology, acquired with Baxalta in June 2016, reported product sales of \$683 million. Immunology includes sales of antibody-replacement immunoglobulin and bio therapeutics therapies. Pro forma Q2 2017 growth in Immunology was approximately 18% (20% at Non GAAP CER) as the franchise benefited from growth in both immunoglobulin therapies and bio therapeutics. The U.S. benefited from growth in demand for our subcutaneous portfolio. International experienced growth across most regions with some benefit due to the timing of large orders.

Neuroscience

Neuroscience product sales decreased 3%, primarily driven by ADDERALL XR.

ADDERALL XR sales decreased 30%, primarily due to additional generic competition since August 2016. VYVANSE sales growth was impacted by destocking in the second quarter of 2017 compared to stocking in the same period in the prior year.

MYDAYIS, approved by the FDA on June 20, 2017, contributed \$16 million of product sales related to launch stocking.

Internal Medicine

Internal Medicine product sales increased 15%, with strong growth from GATTEX/REVESTIVE and NATPARA.

GATTEX/REVESTIVE and NATPARA continued to perform well with sales increasing 69% and 73%, respectively, primarily due to an increase in the numbers of patients on therapy.

During Q2 2017, a generic version of LIALDA was approved by the FDA; Shire expects generic competition to negatively impact future LIALDA product sales.

Oncology

Oncology, acquired with Baxalta in June 2016, reported sales of \$63 million. Oncology includes sales of ONCASPAR and ONIVYDE, the latter of which was approved in the EU on October 18, 2016 and has contributed to international growth in 2017.

Ophthalmology

Ophthalmology product sales relate to XIIDRA, which was made available to patients starting on August 29, 2016. XIIDRA contributed \$57 million of product sales with 13% prescription growth since Q1 2017.

Baxalta pro forma product sales growth

The following table presents Q2 2017 reported legacy Baxalta product sales compared with Q2 2016 pro forma legacy Baxalta sales.

(in millions)				Pro forma Year on year growth	
	U.S. Sales	International Sales	Total Sales	Reported	Non GAAP CER
Product sales by franchise					
HEMOPHILIA	\$ 383.1	\$ 360.8	\$ 743.9	+3%	+5%
INHIBITOR THERAPIES	76.1	144.6	220.7	-7%	-5%
Hematology total	459.2	505.4	964.6	+1%	+2%
IMMUNOGLOBULIN THERAPIES	407.9	102.6	510.5	+19%	+20%
BIO THERAPEUTICS	75.9	96.3	172.2	+18%	+20%
Immunology total	483.8	198.9	682.7	+18%	+20%
Oncology total	45.8	16.7	62.5	+18%	+20%
Total	\$ 988.8	\$ 721.0	\$ 1,709.8	+8%	+9%

2. Royalties and other revenues

(in millions)	Revenue	Year on year growth	
		Reported	Non GAAP CER
SENSIPAR royalties	\$ 46.4	+30%	+31%
ADDERALL XR royalties	13.4	+158%	+157%
FOSRENOL royalties	12.1	+6%	+7%
3TC and ZEFFIX royalties	8.2	-32%	-32%
Other royalties and revenues	73.9	+73%	+77%
Total royalties and other revenues	\$ 154.0	+44%	+46%

Royalties and Other Revenues increased 44%, primarily due to the inclusion of a full quarter of contract manufacturing revenue acquired with Baxalta.

3. Financial details

Cost of sales

(in millions)	Q2 2017	% of total revenues	Q2 2016	% of total revenues
	Cost of sales (US GAAP)	\$ 1,108.9	30%	\$ 778.1
Expense related to the unwind of inventory fair value adjustments	(145.0)		(280.7)	
Depreciation	(67.0)		(22.4)	
Non GAAP cost of sales	\$ 896.9	24%	\$ 475.0	20%

Cost of sales as a percentage of total revenues decreased to 30% 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 increased to 24%, primarily due to the impact of a full quarter of lower margin product franchises acquired with Baxalta.

R&D

(in millions)	Q2 2017	% of total revenues	Q2 2016	% of total revenues
	R&D (US GAAP)	\$ 542.4	14%	\$ 294.8
Impairment of IPR&D intangible assets	(20.0)		(8.9)	
Costs relating to license arrangements	(123.7)		—	
Depreciation	(12.8)		(5.8)	
Non GAAP R&D	\$ 385.9	10%	\$ 280.1	12%

R&D increased by \$248 million, or 84%, primarily due to milestone and upfront payments associated with license arrangements, and the inclusion of a full quarter of Baxalta costs.

Non GAAP R&D increased by \$106 million, or 38%, primarily due to the inclusion of a full quarter of Baxalta costs. Non GAAP R&D expense as a percentage of total revenues decreased 2 percentage points.

SG&A

(in millions)	Q2 2017	% of total revenues	Q2 2016	% of total revenues
SG&A (US GAAP)	\$ 899.1	24%	\$ 675.3	28%
Legal and litigation costs	(7.6)		(1.6)	
Depreciation	(40.9)		(19.7)	
Non GAAP SG&A	\$ 850.6	23%	\$ 654.0	27%

SG&A increased by \$224 million, or 33%, primarily due to the inclusion of a full quarter of Baxalta related costs and increased XIIDRA marketing costs.

Non GAAP SG&A increased by \$197 million, or 30%, primarily due to the inclusion of a full quarter of Baxalta related costs and increased XIIDRA marketing costs. Non GAAP SG&A as a percentage of total revenues decreased 4 percentage points.

Amortization of acquired intangible assets

Shire recorded amortization of acquired intangible assets of \$434 million (Q2 2016: \$213 million). The increase is primarily related to amortization on the intangible assets acquired with the Baxalta transaction.

Integration and acquisition costs

In Q2 2017, Shire recorded integration and acquisition costs of \$344 million. Integration costs of \$193 million, primarily related to Baxalta, including employee severance and acceleration of stock compensation, third-party professional fees and expenses associated with facility consolidations. Additionally, integration and acquisition costs included a net charge of \$151 million, relating to the change in fair value of contingent consideration, primarily related to SHP643 which was acquired from Dyax in 2016.

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 included costs relating to investment banking and other transaction-related fees, as well as integration costs related to employee severance and acceleration of stock compensation, and third-party professional fees. These costs were partially offset by a net credit of \$58 million relating to the change in fair value of contingent consideration.

Other expense, net

(in millions)	Q2 2017	Q2 2016
Other expense, net (US GAAP)	\$ (137.7)	\$ (79.6)
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	1.7	25.9
Gain on sale of long term investments	(13.2)	—
Non GAAP Other expense, net	\$ (149.2)	\$ (53.7)

Other expense, net increased by \$58 million, primarily due to higher interest expense incurred on borrowings used to fund the acquisitions of Dyax and Baxalta.

Non GAAP Other expense, net increased by \$96 million, primarily due to higher interest expense as noted above.

Taxation

(in millions)	Q2 2017	Effective tax rate	Q2 2016	Effective tax rate
Income tax expense (US GAAP)	\$ (24.3)	9%	\$ 70.9	(427%)
Tax effect of adjustments	(187.6)		(215.8)	
Non GAAP Income tax expense	\$ (211.9)	16%	\$ (144.9)	16%

The effective tax rate on US GAAP income in Q2 2017 was 9% (Q2 2016: -427%) and on a Non GAAP basis was 16% (Q2 2016: 16%).

The effective rate in Q2 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 and the reversal of deferred tax liabilities from the Baxalta acquisition, as well as acquisition and integration costs in higher tax territories.

Discontinued operations

The loss from discontinued operations in Q2 2017 was \$1 million, net of taxes, associated with the divested DERMAGRAFT business. The loss in Q2 2016 was \$249 million, net of taxes of \$101 million, primarily due to the establishment of legal contingencies related to the divested DERMAGRAFT business.

FINANCIAL INFORMATION

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Unaudited US GAAP Consolidated Balance Sheets
(in millions, except par value of shares)

	June 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 263.7	\$ 528.8
Restricted cash	34.2	25.6
Accounts receivable, net	2,755.2	2,616.5
Inventories	3,325.3	3,562.3
Prepaid expenses and other current assets	778.5	806.3
Total current assets	7,156.9	7,539.5
Non-current assets:		
Investments	197.0	191.6
Property, plant and equipment (PP&E), net	6,554.5	6,469.6
Goodwill	19,482.1	17,888.2
Intangible assets, net	33,434.3	34,697.5
Deferred tax asset	132.2	96.7
Other non-current assets	233.9	152.3
Total assets	\$ 67,190.9	\$ 67,035.4
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,842.0	\$ 4,312.4
Short term borrowings and capital leases	3,204.9	3,068.0
Other current liabilities	389.6	362.9
Total current liabilities	7,436.5	7,743.3
Non-current liabilities:		
Long term borrowings and capital leases	18,355.1	19,899.8
Deferred tax liability	7,788.0	8,322.7
Other non-current liabilities	2,346.2	2,121.6
Total liabilities	35,925.8	38,087.4
Equity:		
Common stock of 5p par value; 1,500 shares authorized; and 915.3 shares issued and outstanding (2016: 1,500 shares authorized; and 912.2 shares issued and outstanding)	81.5	81.3
Additional paid-in capital	24,951.2	24,740.9
Treasury stock: 8.4 shares (2016: 9.1 shares)	(283.0)	(301.9)
Accumulated other comprehensive income/(loss)	200.1	(1,497.6)
Retained earnings	6,315.3	5,925.3
Total equity	31,265.1	28,948.0
Total liabilities and equity	\$ 67,190.9	\$ 67,035.4

Unaudited US GAAP Consolidated Statements of Operations

(in millions)

	3 months ended June 30,		6 months ended June 30,	
	2017	2016	2017	2016
Revenues:				
Product sales	\$ 3,591.8	\$ 2,322.1	\$ 7,004.1	\$ 3,949.4
Royalties & other revenues	154.0	107.0	314.0	189.0
Total revenues	3,745.8	2,429.1	7,318.1	4,138.4
Costs and expenses:				
Cost of sales	1,108.9	778.1	2,435.9	1,026.7
Research and development	542.4	294.8	921.7	511.9
Selling, general and administrative	899.1	675.3	1,788.0	1,150.2
Amortization of acquired intangible assets	434.1	213.0	798.1	347.6
Integration and acquisition costs	343.7	363.0	459.7	454.1
Reorganization costs	13.6	11.0	19.1	14.3
Loss/(gain) on sale of product rights	4.8	(2.3)	(0.7)	(6.5)
Total operating expenses	3,346.6	2,332.9	6,421.8	3,498.3
Operating income from continuing operations	399.2	96.2	896.3	640.1
Interest income	1.1	1.6	4.2	2.6
Interest expense	(141.3)	(87.2)	(283.6)	(131.9)
Other income/(expense), net	2.5	6.0	7.0	(2.5)
Total other expense, net	(137.7)	(79.6)	(272.4)	(131.8)
Income from continuing operations before income taxes and equity in earnings/(losses) of equity method investees	261.5	16.6	623.9	508.3
Income taxes	(24.3)	70.9	(31.1)	(11.2)
Equity in earnings/(losses) of equity method investees, net of taxes	4.3	(0.9)	3.5	(1.0)
Income from continuing operations, net of taxes	241.5	86.6	596.3	496.1
(Loss)/gain from discontinued operations, net of taxes	(1.2)	(248.7)	19.0	(239.2)
Net income/(loss)	\$ 240.3	\$ (162.1)	\$ 615.3	\$ 256.9

Unaudited US GAAP Consolidated Statements of Operations (continued)

(in millions, except per share amounts)

	3 months ended June 30,		6 months ended June 30,	
	2017	2016	2017	2016
Earnings/(loss) per Ordinary Share – basic				
Earnings from continuing operations	\$ 0.27	\$ 0.12	\$ 0.66	\$ 0.78
(Loss)/gain from discontinued operations	—	(0.36)	0.02	(0.38)
Earnings/(loss) per Ordinary Share – basic	\$ 0.27	\$ (0.24)	\$ 0.68	\$ 0.40
Earnings/(loss) per ADS – basic	\$ 0.80	\$ (0.71)	\$ 2.04	\$ 1.21
Earnings/(loss) per Ordinary Share – diluted				
Earnings from continuing operations	\$ 0.26	\$ 0.12	\$ 0.65	\$ 0.77
(Loss)/earnings from discontinued operations	—	(0.36)	0.02	(0.37)
Earnings/(loss) per Ordinary Share – diluted	\$ 0.26	\$ (0.24)	\$ 0.67	\$ 0.40
Earnings/(loss) per ADS – diluted	\$ 0.79	\$ (0.71)	\$ 2.02	\$ 1.20
Weighted average number of shares:				
Basic	906.4	682.8	905.3	637.3
Diluted	912.7	682.8	912.3	640.1

Unaudited US GAAP Consolidated Statements of Cash Flows

(in millions)

	3 months ended June 30,		6 months ended June 30,	
	2017	2016	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net income/(loss)	\$ 240.3	\$ (162.1)	\$ 615.3	\$ 256.9
Adjustments to reconcile net income/(loss) to net cash provided by operating activities:				
Depreciation and amortization	554.8	260.9	1,041.7	429.8
Share based compensation	53.7	176.5	106.4	194.8
Amortization of deferred financing fees	3.6	30.1	6.8	50.1
Expense related to the unwind of inventory fair value adjustments	145.0	280.7	625.4	293.5
Change in deferred taxes	(157.8)	(319.1)	(293.3)	(329.2)
Change in fair value of contingent consideration	151.2	(56.4)	147.7	(45.0)
Impairment of PP&E and intangible assets	53.6	8.9	53.6	8.9
Other, net	(12.0)	(3.1)	14.8	(17.6)
Changes in operating assets and liabilities:				
Increase in accounts receivable	(146.2)	(80.1)	(181.5)	(181.0)
Increase/(decrease) in sales deduction accrual	39.6	(7.2)	57.1	66.4
Increase in inventory	(19.8)	(84.2)	(171.6)	(116.4)
Decrease in prepayments and other assets	90.4	48.7	104.6	26.5
Increase/(decrease) in accounts payable and other liabilities	226.4	497.3	(445.1)	342.7
Net cash provided by operating activities	1,222.8	590.9	1,681.9	980.4
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of PP&E and long term investments	(178.6)	(127.5)	(391.1)	(179.1)
Purchases of businesses, net of cash acquired	—	(11,783.4)	—	(17,476.2)
Proceeds from sale of investments	40.6	—	40.6	—
Movements in restricted cash	(0.1)	2.4	(8.6)	67.2
Other, net	2.0	(2.2)	3.2	3.3
Net cash used in investing activities	(136.1)	(11,910.7)	(355.9)	(17,584.8)

Unaudited US GAAP Consolidated Statements of Cash Flows (continued)

(in millions)

	3 months ended June 30,		6 months ended June 30,	
	2017	2016	2017	2016
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from revolving line of credit, long term and short term borrowings	710.0	12,590.0	2,111.9	18,895.0
Repayment of revolving line of credit, long term and short term borrowings	(1,702.2)	(505.2)	(3,527.9)	(1,500.3)
Payment of dividend	(234.7)	(130.2)	(234.7)	(130.2)
Debt issuance costs	—	(18.5)	—	(112.3)
Proceeds from exercise of options	37.4	—	79.5	0.1
Other, net	(3.9)	11.0	(24.0)	11.9
Net cash (used in)/provided by financing activities	(1,193.4)	11,947.1	(1,595.2)	17,164.2
Effect of foreign exchange rate changes on cash and cash equivalents	1.4	(2.9)	4.1	(1.9)
Net (decrease)/increase in cash and cash equivalents	(105.3)	624.4	(265.1)	557.9
Cash and cash equivalents at beginning of period	369.0	69.0	528.8	135.5
Cash and cash equivalents at end of period	\$ 263.7	\$ 693.4	\$ 263.7	\$ 693.4

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,	
	2017	2016	2017	2016
Income from continuing operations	\$ 241.5	\$ 86.6	\$ 596.3	\$ 496.1
(Loss)/gain from discontinued operations	(1.2)	(248.7)	19.0	(239.2)
Numerator for EPS	\$ 240.3	\$ (162.1)	\$ 615.3	\$ 256.9
Weighted average number of shares:				
Basic	906.4	682.8	905.3	637.3
Effect of dilutive shares:				
Share based awards to employees	6.3	—	7.0	2.8
Diluted	912.7	682.8	912.3	640.1
The share equivalents not included in the calculation of the diluted weighted average number of shares are shown below:				
Share based awards to employees	13.2	8.3	10.3	4.4

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,	
	2017	2016	2017	2016
Product sales by franchise				
HEMOPHILIA	\$ 743.9	\$ 275.6	\$ 1,394.3	\$ 275.6
INHIBITOR THERAPIES	220.7	74.0	441.2	74.0
Hematology	964.6	349.6	1,835.5	349.6
CINRYZE	175.9	173.0	401.8	337.2
ELAPRASE	161.0	154.0	301.6	277.6
FIRAZYR	137.4	136.7	265.9	265.0
REPLAGAL	122.1	118.4	231.8	221.6
VPRIV	87.9	88.0	167.7	171.6
KALBITOR	20.6	17.7	32.3	28.1
Genetic Diseases	704.9	687.8	1,401.1	1,301.1
IMMUNOGLOBULIN THERAPIES	510.5	138.2	1,008.8	138.2
BIO THERAPEUTICS	172.2	51.3	350.1	51.3
Immunology	682.7	189.5	1,358.9	189.5
VYVANSE	518.2	517.7	1,081.9	1,026.9
ADDERALL XR	71.4	101.8	136.3	200.6
MYDAYIS	15.7	—	15.7	—
Other Neuroscience	30.1	35.7	54.8	57.8
Neuroscience	635.4	655.2	1,288.7	1,285.3
LIALDA/MEZAVANT	207.8	193.7	382.9	361.7
PENTASA	83.3	72.9	152.4	136.9
GATTEX/REVESTIVE	75.3	44.5	144.3	96.2
NATPARA	34.5	19.9	64.2	35.5
Other Internal Medicine	83.4	88.7	159.3	173.3
Internal Medicine	484.3	419.7	903.1	803.6
Oncology	62.5	20.3	120.8	20.3
Ophthalmology	57.4	—	96.0	—
Total product sales	3,591.8	2,322.1	7,004.1	3,949.4
Royalties and other revenues				
SENSIPAR royalties	46.4	35.6	85.3	73.5
ADDERALL XR royalties	13.4	5.2	25.9	11.0
FOSRENOL royalties	12.1	11.4	20.7	20.6
3TC and ZEFFIX royalties	8.2	12.1	22.7	27.1
Other Royalties and revenues	73.9	42.7	159.4	56.8
Total royalties and other revenues	154.0	107.0	314.0	189.0
Total revenues	\$ 3,745.8	\$ 2,429.1	\$ 7,318.1	\$ 4,138.4

Non GAAP reconciliations

(in millions)

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

	3 months ended June 30,		6 months ended June 30,	
	2017	2016	2017	2016
US GAAP net income/(loss)	\$ 240.3	\$ (162.1)	\$ 615.3	\$ 256.9
Add back/(deduct):				
Loss/(gain) from discontinued operations, net of tax	1.2	248.7	(19.0)	239.2
Equity in (earnings)/losses of equity method investees, net of taxes	(4.3)	0.9	(3.5)	1.0
Income taxes	24.3	(70.9)	31.1	11.2
Other expense, net	137.7	79.6	272.4	131.8
US GAAP operating income from continuing operations	399.2	96.2	896.3	640.1
Add back/(deduct) Non GAAP adjustments:				
Expense related to the unwind of inventory fair value adjustments	145.0	280.7	625.4	293.5
Impairment of acquired intangible assets	20.0	8.9	20.0	8.9
Costs relating to license arrangements	123.7	—	123.7	—
Legal and litigation costs	7.6	1.6	7.6	16.6
Amortization of acquired intangible assets	434.1	213.0	798.1	347.6
Integration and acquisition costs	343.7	363.0	459.7	454.1
Reorganization costs	13.6	11.0	19.1	14.3
Loss/(gain) on sale of product rights	4.8	(2.3)	(0.7)	(6.5)
Depreciation	120.7	47.9	243.6	82.2
Other Non GAAP adjustments	—	—	(4.0)	—
Non GAAP EBITDA	1,612.4	1,020.0	3,188.8	1,850.8
Depreciation	(120.7)	(47.9)	(243.6)	(82.2)
Non GAAP operating income	\$ 1,491.7	\$ 972.1	\$ 2,945.2	\$ 1,768.6
Net income margin⁽¹⁾	6%	(7)%	8%	6%
Non GAAP EBITDA margin⁽²⁾	43%	42 %	44%	45%

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

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

Reconciliation of revenues to Non GAAP gross margin:

	3 months ended June 30,		6 months ended June 30,	
	2017	2016	2017	2016
Revenues	\$ 3,745.8	\$ 2,429.1	\$ 7,318.1	\$ 4,138.4
Cost of sales (US GAAP)	(1,108.9)	(778.1)	(2,435.9)	(1,026.7)
US GAAP gross margin	2,636.9	1,651.0	4,882.2	3,111.7
Add back Non GAAP adjustments:				
Expense related to the unwind of inventory fair value adjustments	145.0	280.7	625.4	293.5
Depreciation	67.0	22.4	139.1	30.7
Non GAAP gross margin	\$ 2,848.9	\$ 1,954.1	\$ 5,646.7	\$ 3,435.9
Non GAAP gross margin %⁽¹⁾	76.1%	80.4%	77.2%	83.0%

⁽¹⁾ Non GAAP gross margin as a percentage of total revenues.

Non GAAP reconciliations

(in millions, except per ADS amounts)

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

	3 months ended June 30,		6 months ended June 30,	
	2017	2016	2017	2016
US GAAP net income/(loss)	\$ 240.3	\$ (162.1)	\$ 615.3	\$ 256.9
Expense related to the unwind of inventory fair value adjustments	145.0	280.7	625.4	293.5
Impairment of acquired intangible assets	20.0	8.9	20.0	8.9
Costs relating to license arrangements	123.7	—	123.7	—
Legal and litigation costs	7.6	1.6	7.6	16.6
Amortization of acquired intangible assets	434.1	213.0	798.1	347.6
Integration and acquisition costs	343.7	363.0	459.7	454.1
Reorganization costs	13.6	11.0	19.1	14.3
Loss/(gain) on sale of product rights	4.8	(2.3)	(0.7)	(6.5)
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	1.7	25.9	3.5	44.1
(Gain)/loss on sale of long term investments	(13.2)	—	(13.2)	6.0
Loss/(gain) from discontinued operations	1.9	349.6	(29.9)	334.6
Other Non GAAP adjustments	—	—	(4.0)	—
Tax effect of adjustments	(188.3)	(316.7)	(387.6)	(365.7)
Non GAAP net income	\$ 1,134.9	\$ 772.6	\$ 2,237.0	\$ 1,404.4

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,	
	2017	2016	2017	2016
US GAAP diluted earnings/(losses) per ADS	\$ 0.79	\$ (0.71)	\$ 2.02	\$ 1.20
Expense related to the unwind of inventory fair value adjustments	0.48	1.23	2.06	1.38
Impairment of acquired intangible assets	0.07	0.04	0.07	0.04
Costs relating to license arrangements	0.41	—	0.41	—
Legal and litigation costs	0.02	0.01	0.02	0.08
Amortization of acquired intangible assets	1.42	0.94	2.62	1.63
Integration and acquisition costs	1.12	1.59	1.51	2.13
Reorganization costs	0.04	0.05	0.06	0.07
Loss/(gain) on sale of product rights	0.02	(0.01)	—	(0.03)
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	0.01	0.11	0.01	0.21
(Gain)/loss on sale of long term investments	(0.04)	—	(0.04)	0.03
Loss/(gain) from discontinued operations	0.01	1.53	(0.10)	1.56
Other Non GAAP adjustments	—	—	(0.01)	—
Tax effect of adjustments	(0.62)	(1.40)	(1.27)	(1.72)
Non GAAP diluted earnings per ADS	\$ 3.73	\$ 3.38	\$ 7.36	\$ 6.58

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 June 30,		6 months ended June 30,	
	2017	2016	2017	2016
Net cash provided by operating activities	\$ 1,222.8	\$ 590.9	\$ 1,681.9	\$ 980.4
Capital expenditure	(178.6)	(127.5)	(391.1)	(179.1)
Up-front payments for in-licensed products	20.0	—	20.0	—
Non GAAP free cash flow	\$ 1,064.2	\$ 463.4	\$ 1,310.8	\$ 801.3

Non GAAP net debt comprises:

	June 30, 2017	December 31, 2016
Cash and cash equivalents	\$ 263.7	\$ 528.8
Long term borrowings (excluding capital leases)	(18,011.3)	(19,552.6)
Short term borrowings (excluding capital leases)	(3,198.1)	(3,061.6)
Capital leases	(350.6)	(353.6)
Non GAAP net debt	\$ (21,296.3)	\$ (22,439.0)

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

	Full Year 2017 Outlook	
	Min	Max
US GAAP diluted earnings per ADS	\$ 5.65	\$ 6.05
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)
Tax effect of adjustments		(2.43)
Non GAAP diluted earnings per ADS	\$ 14.80	\$ 15.20

NOTES TO EDITORS

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

Inside Information

This announcement contains inside information.

About Shire

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

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

www.shire.com

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

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

- Shire’s products may not be a commercial success;
- increased pricing pressures and limits on patient access as a result of governmental regulations and market developments may affect Shire’s future revenues, financial condition and results of operations;
- Shire conducts its own manufacturing operations for certain of its products and is reliant on third party contract manufacturers to manufacture other products and to provide goods and services. Some of Shire’s products or ingredients are only available from a single approved source for manufacture. Any disruption to the supply chain for any of Shire’s products may result in Shire being unable to continue marketing or developing a product or may result in Shire being unable to do so on a commercially viable basis for some period of time;
- the manufacture of Shire’s products is subject to extensive oversight by various regulatory agencies. Regulatory approvals or interventions associated with changes to manufacturing sites, ingredients or manufacturing processes could lead to, among other things, significant delays, an increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- certain of Shire’s therapies involve lengthy and complex processes, which may prevent Shire from timely responding to market forces and effectively managing its production capacity;
- Shire has a portfolio of products in various stages of research and development. The successful development of these products is highly uncertain and requires significant expenditures and time, and there is no guarantee that these products will receive regulatory approval;
- the actions of certain customers could affect Shire’s ability to sell or market products profitably. Fluctuations in buying or distribution patterns by such customers can adversely affect Shire’s revenues, financial conditions or results of operations;
- Shire’s products and product candidates face substantial competition in the product markets in which it operates, including competition from generics;
- adverse outcomes in legal matters, tax audits and other disputes, including Shire’s ability to enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on the Company’s revenues, financial condition or results of operations;
- inability to successfully compete for highly qualified personnel from other companies and organizations;
- failure to achieve the strategic objectives, including expected operating efficiencies, cost savings, revenue enhancements, synergies or other benefits at the time anticipated or at all with respect to Shire’s acquisitions, including NPS Pharmaceuticals Inc., Dyax Corp. or Baxalta Incorporated may adversely affect Shire’s financial condition and results of operations;
- Shire’s growth strategy depends in part upon its ability to expand its product portfolio through external collaborations, which, if unsuccessful, may adversely affect the development and sale of its products;
- a slowdown of global economic growth, or economic instability of countries in which Shire does business, as well as changes in foreign currency exchange rates and interest rates, that adversely impact the availability and cost of credit and customer purchasing and payment patterns, including the collectability of customer accounts receivable;
- failure of a marketed product to work effectively or if such a product is the cause of adverse side effects could result in damage to Shire’s reputation, the withdrawal of the product and legal action against Shire;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to Shire’s activities in the highly regulated markets in which it operates may result in significant legal costs and the payment of substantial compensation or fines;
- Shire is dependent on information technology and its systems and infrastructure face certain risks, including from service disruptions, the loss of sensitive or confidential information, cyber-attacks and other security breaches or data leakages that could have a material adverse effect on Shire’s revenues, financial condition or results of operations;
- Shire incurred substantial additional indebtedness to finance the Baxalta acquisition, which 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 22 to 24.

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 June 30, 2017 were \$1.28:£1.00 and \$1.09:€1.00 (2016: \$1.45:£1.00 and \$1.13:€1.00). Average exchange rates used by Shire for the six months ended June 30, 2017 were \$1.26:£1.00 and \$1.08:€1.00 (2016: \$1.44:£1.00 and \$1.11:€1.00).

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