

Press Release



Shire Delivers Q2 2018 Product Sales Growth of 6% and Continued Regulatory and Pipeline Progress

Product sales grew to \$3.8 billion driven by Immunology, recently launched products, and international expansion

Innovative pipeline continued to advance with 7 programs in registration and 16 in Phase 3

U.S. Food and Drug Administration (FDA) approval received for state-of-the-art plasma manufacturing facility

\$0.9 billion in net operating cash flow enabled continued debt pay-down

July 31, 2018 – Shire plc (Shire) (LSE: SHP, NASDAQ: SHPG), the leading global biotech company focused on rare diseases, announces unaudited results for the three months ended June 30, 2018.

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

"Shire continued to deliver on its key priorities of commercial execution, pipeline advancement, debt pay-down, and portfolio optimization during the second quarter. We drove product sales growth of 6% over the prior year period led by the strong performance of our Immunology franchise, continued uptake of our recently launched products, and expansion in international markets.

"During the quarter, our Board reached an agreement with the Takeda Board on the terms of a recommended offer for Takeda to acquire Shire. The acquisition is expected to close in H1 2019, subject to shareholder approval of both companies and additional regulatory approvals. In the meantime, we remain resolutely focused on execution as these results demonstrate.

"We also achieved important regulatory milestones and continued to advance our robust late stage pipeline. We received U.S. FDA approval for CINRYZE for pediatric use and a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) recommending marketing authorization for VEYVONDI in Europe. In addition, we gained U.S. FDA approval for our state-of-the-art plasma manufacturing facility near Covington, Georgia supporting the continued growth of our immunoglobulin portfolio."

Financial Highlights

	Q2 2018	Reported Growth	Non GAAP CER ⁽¹⁾
Product sales ⁽²⁾	\$3,809 million	+6%	+4%
Total revenues ⁽²⁾	\$3,920 million	+5%	+3%
Operating income from continuing operations	\$830 million	+108%	
Non GAAP operating income ⁽¹⁾	\$1,492 million	+0%	-1%
Net income margin ⁽³⁾⁽⁴⁾	16%	+10ppc	
Non GAAP EBITDA margin ⁽¹⁾⁽³⁾⁽⁴⁾	42%	-1ppc	
Net income	\$616 million	+156%	
Non GAAP net income ⁽¹⁾	\$1,186 million	+4%	
Diluted earnings per ADS ⁽⁵⁾	\$2.01	+154%	
Non GAAP diluted earnings per ADS ⁽¹⁾⁽⁵⁾	\$3.88	+4%	+2%
Net cash provided by operating activities	\$940 million	-23%	
Non GAAP free cash flow ⁽¹⁾	\$756 million	-29%	

⁽¹⁾ 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 U.S. GAAP on pages 20 – 23.

⁽²⁾ In Q2 2018, we returned to a single segment approach to managing our business. This decision was precipitated by our Board's acceptance of Takeda's offer to acquire Shire and reflects our focus on the performance of the entire business as it operates in this current environment.

⁽³⁾ Percentage point change (ppc).

⁽⁴⁾ Calculated as a percentage of total revenues.

⁽⁵⁾ Diluted weighted average number of ordinary shares of 917.5 million.

Product sales growth

- Achieved product sales growth of 6% driven primarily by Immunology, Internal Medicine, and Ophthalmics. Excluding the impact of Established Brands, defined on page 8, product sales increased 10%.
- Delivered growth of recently launched products of 67%, primarily due to ADYNOVATE, CUVITRU, GATTEX, and XIIDRA.
- Strong demand for our Immunology products which delivered 13% growth, including significant contributions from our subcutaneous immunoglobulin portfolio.

Operating performance

- Generated Non GAAP diluted earnings per ADS of \$3.88, an increase of 4%, as Q2 2018 benefited from higher product sales, partially offset by lower gross margins as Q2 2017 reflected favorability from the timing of changes in the costs to manufacture certain products.
- Reported Non GAAP EBITDA margin of 42%, a slight decline from Q2 2017, with continued benefit from operating efficiencies in SG&A offset by lower gross margins as explained above.

Cash flow

- Strong free cash flow enabled a \$1,414 million reduction in Non GAAP net debt since December 31, 2017.

FINANCIAL SUMMARY - SECOND QUARTER 2018 COMPARED TO SECOND QUARTER 2017

Revenues

- Delivered total revenues of \$3,920 million representing growth of 5%.
- Product sales increased 6% to \$3,809 million (Q2 2017: \$3,592 million), driven by Immunology, up 13%, Internal Medicine, up 61%, and Ophthalmics, up 75%. Excluding the impact of Established Brands, product sales increased 10%.
- Royalties and other revenues decreased 28% to \$111 million (Q2 2017: \$154 million), due to lower SENSIPAR royalties and the reclassification of ADDERALL XR from royalty revenue to product sales and other changes as required under the new revenue accounting standard.

Operating results

- Operating income increased 108% to \$830 million (Q2 2017: \$399 million), due to a decline in integration and acquisition costs and lower expense related to the unwind of inventory fair value adjustments. Q2 2017 also reflected costs related to R&D license arrangements which did not recur in Q2 2018.
- Non GAAP operating income was unchanged at \$1,492 million (Q2 2017: \$1,492 million), primarily due to increased product sales, partially offset by lower gross margins due to Q2 2017 favorability from the timing of changes in the costs to manufacture certain products.
- Non GAAP EBITDA margin was slightly down to 42% (Q2 2017: 43%), primarily due to lower gross margin partially offset by benefits from ongoing cost reduction initiatives and operating expense synergies.

Earnings per share (EPS)

- Diluted earnings per American Depositary Share (ADS) increased 154% to \$2.01 (Q2 2017: \$0.79), due to a decline in integration and acquisition costs and lower expense related to the unwind of inventory fair value adjustments. Q2 2017 also reflected costs related to R&D license arrangements which did not recur in Q2 2018.
- Non GAAP diluted earnings per ADS increased 4% to \$3.88 (Q2 2017: \$3.73) as increased product sales were offset by lower gross margins.

Cash flows

- Net cash provided by operating activities decreased 23% to \$940 million (Q2 2017: \$1,223 million), primarily driven by tax payments during the quarter of \$380 million (Q2 2017: \$153 million), due to higher taxable income and timing of tax payments.
- Non GAAP free cash flow decreased 29% to \$756 million (Q2 2017: \$1,064 million), primarily due to the decrease in net cash provided by operating activities noted above. Non GAAP free cash flow includes capital expenditures of \$184 million (Q2 2017: \$179 million).

Debt

- Non GAAP net debt as of June 30, 2018 decreased \$1,414 million since December 31, 2017, to \$17,655 million (December 31, 2017: \$19,069 million). A combination of Shire's Non GAAP free cash flow and existing cash balances were utilized to repay debt during the year. Non GAAP net debt represents aggregate long and short term borrowings of \$17,568 million, and capital leases of \$347 million, partially offset by cash and cash equivalents of \$260 million.

OUTLOOK

Our 2018 guidance, which continues to include our Oncology franchise, remains unchanged. Guidance will be updated to remove the Oncology franchise after the close of the sale to Servier S.A.S. (Servier), which is expected in Q3 2018. Similarly, our 2020 guidance remains unchanged and will be updated to remove the Oncology franchise after the close of this pending sale.

The Non GAAP diluted earnings per ADS forecast assumes a weighted average number of 915 million fully diluted ordinary shares outstanding for 2018.

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

Risks associated with this outlook include the potential uncertainty resulting from the announcement by Takeda Pharmaceutical Company Limited (Takeda) on May 8, 2018 of a recommended offer for Shire under the U.K. Takeover Code.

Full Year 2018	U.S. GAAP Outlook	Non GAAP Outlook ⁽¹⁾
Total revenue ⁽²⁾	\$15.4 - \$15.9 billion	\$15.4 - \$15.9 billion
Gross margin as a percentage of total revenue ⁽³⁾	71.0% - 73.0%	73.5% - 75.5%
Combined R&D and SG&A	\$5.2 - \$5.4 billion	\$4.9 - \$5.1 billion
Net interest/other	\$450 - \$550 million	\$450 - \$550 million
Effective tax rate	15% - 17%	16% - 18%
Diluted earnings per ADS ⁽⁴⁾	\$7.30 - \$7.90	\$14.90 - \$15.50

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

⁽²⁾ Management is providing guidance for total revenue. Total revenue is comprised of total product sales and royalties & other revenues. Pursuant to a change in U.S. GAAP related to accounting for revenue, certain revenue formerly classified as royalties are now recorded as product sales.

⁽³⁾ Gross margin as a percentage of total revenues excludes amortization of acquired intangible assets.

⁽⁴⁾ See page 23 for a reconciliation between U.S. GAAP diluted earnings per ADS and Non GAAP diluted earnings per ADS.

RECENT DEVELOPMENTS

Corporate

- On May 8, 2018, the Boards of Takeda and Shire announced that they had reached agreement on the terms of a recommended offer pursuant to which Takeda will acquire the entire issued and to be issued ordinary share capital of Shire. The acquisition is expected to close in H1 2019, subject to a number of conditions, including receipt of regulatory clearances and approval by the shareholders of both companies.

Business Development

Sale of Oncology franchise

- On April 16, 2018, Shire announced it had entered into a definitive agreement with Servier to sell its Oncology franchise for \$2.4 billion. Activities to conclude the sale are on track and the closing of the transaction is expected to occur in Q3 2018.

Products

VEYVONDI for adults with von Willebrand disease (VWD)

- On July 2, 2018, Shire announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) had issued a positive opinion recommending the granting of a marketing authorization in the European Union (EU) for VEYVONDI, for the treatment of bleeding events and treatment/prevention of surgical bleeding in adults (age 18 and older) with VWD.

CINRYZE for the prevention of attacks in pediatric HAE patients

- On June 21, 2018, Shire announced that the FDA had approved a label expansion for CINRYZE, making it available to help prevent angioedema attacks in children aged 6 years and older with HAE.

XIIDRA for the treatment of the signs and symptoms of dry eye disease

- In June 2018, Shire withdrew from the decentralized procedure for XIIDRA's European Marketing Authorization Application and is targeting Q4 2018 for resubmission through a centralized procedure.

Pipeline

SHP626, an investigational treatment for adults with nonalcoholic steatohepatitis (NASH) with liver fibrosis

- In June 2018, Shire announced that the phase 2 clinical study of SHP626 has been discontinued. Shire is evaluating other options for the program.

Facilities

- On June 21, 2018, Shire announced that the FDA had approved its submission for the production of GAMMAGARD LIQUID at its new plasma manufacturing facility near Covington, Georgia. The facility will add approximately 30% capacity to Shire's internal network once fully operational. Commercial production began in January 2018 and shipments commenced shortly after approval.

Dividend

In respect of the six months ended June 30, 2018, the Board resolved to pay an interim dividend of 5.60 U.S. cents per Ordinary Share (2017: 5.09 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 4.26⁽¹⁾ pence per Ordinary Share (2017: 3.85 pence) and 16.80 U.S. cents per ADS (2017: 15.27 U.S. cents) will be paid on October 19, 2018, to shareholders on the register as of the close of business on September 7, 2018.

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 21, 2018. 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 1.3147.

ADDITIONAL INFORMATION

The following additional information is included in this press release:

	Page
Overview of Second Quarter 2018 Financial Results	8
Financial Information	12
Non GAAP Reconciliations	20
Notes to Editors	24
Forward-Looking Statements	25
Non GAAP Measures	27
Trademarks	28

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Dial in details for the **live conference call** for investors at 14:00 BST / 9:00 EDT on July 31, 2018:

U.K. dial in:	0800 358 9473 or +44 333 300 0804
U.S. dial in:	1 855 857 0686 or 1 631 913 1422
International Access Numbers:	Click here
Password/Conf ID:	45131838 #
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 2018 FINANCIAL RESULTS COMPARED TO SECOND QUARTER 2017

In Q2 2018, we returned to a single segment approach to managing our business. This decision was precipitated by our Board's acceptance of Takeda's offer to acquire Shire and reflects our focus on the performance of the entire business as it operates in this current environment. This step was taken to more closely align with how the financial information is viewed by the Executive Committee (Shire's chief operating decision maker) for the purposes of making resource allocation decisions and assessing the performance of the business. Additionally, in Q2 2018, we introduced a new product franchise called Established Brands to capture revenue for our non-promoted products that are facing or could face generic competition, such as LIALDA and PENTASA.

1. Product sales

Product sales increased 6% to \$3,809 million (Q2 2017: \$3,592 million), driven by Immunology, up 13%, Internal Medicine, up 61%, and Ophthalmics, up 75%, off-setting the impact of generic competition on Established Brands.

(in millions)				Total Sales Year on year growth	
Product sales by franchise	U.S. Sales	International Sales	Total Sales	Reported	Non GAAP CER
IMMUNOGLOBULIN THERAPIES	\$ 457.3	\$ 154.8	\$ 612.1	+20%	+19%
HEREDITARY ANGIOEDEMA	326.2	39.0	365.2	+9%	+9%
BIO THERAPEUTICS	80.4	91.8	172.2	0%	-2%
Immunology	863.9	285.6	1,149.5	+13%	+12%
HEMOPHILIA	372.9	373.8	746.7	+0%	-2%
INHIBITOR THERAPIES	55.2	149.1	204.3	-7%	-11%
Hematology	428.1	522.9	951.0	-1%	-4%
VYVANSE	486.6	69.4	556.0	+7%	+7%
ADDERALL XR	75.7	4.1	79.8	+12%	+11%
MYDAYIS	16.6	—	16.6	N/M	N/M
Other Neuroscience ⁽¹⁾	4.3	37.0	41.3	+37%	+30%
Neuroscience	583.2	110.5	693.7	+9%	+8%
ELAPRASE	43.8	132.7	176.5	+10%	+7%
REPLAGAL	—	125.6	125.6	+3%	-2%
VPRIV	38.2	51.4	89.6	+2%	-1%
Genetic Diseases	82.0	309.7	391.7	+6%	+2%
GATTEX/REVESTIVE	117.6	15.9	133.5	+77%	+76%
NATPARA/NATPAR	62.4	2.4	64.8	+88%	+87%
Other Internal Medicine ⁽²⁾	0.2	34.4	34.6	-2%	-9%
Internal Medicine	180.2	52.7	232.9	+61%	+58%
LIALDA/MEZAVANT	75.4	30.5	105.9	-49%	-50%
PENTASA	77.5	—	77.5	-7%	-7%
Other Established Brands ⁽³⁾	12.8	22.3	35.1	-27%	-30%
Established Brands	165.7	52.8	218.5	-36%	-36%
Ophthalmics	99.2	1.1	100.3	+75%	+75%
Oncology	47.9	23.1	71.0	+14%	+11%
Total product sales	\$ 2,450.2	\$ 1,358.4	\$ 3,808.6	+6%	+4%

⁽¹⁾ Other Neuroscience includes INTUNIV, EQUASYM, and BUCCOLAM.

⁽²⁾ Other Internal Medicine includes AGRYLIN, PLENADREN, and RESOLOR.

⁽³⁾ Other Established Brands includes FOSRENOL and CARBATROL.

Immunology

Immunology product sales were \$1,150 million in Q2 2018. Immunoglobulin therapies growth of 20% was primarily driven by increased demand for subcutaneous and intravenous brands, and timing of large orders in international markets. HAE product sales were up 9% driven by stocking for both CINRYZE and FIRAZYR, as well as FIRAZYR demand growth, partially offset by a decline in CINRYZE demand due to a competitor launch. Bio therapeutics sales were unchanged year over year as increased demand was offset by large order phasing in international markets.

Hematology

Hematology product sales were \$951 million in Q2 2018. Sales of our inhibitor therapies declined 7% due to new competition, while sales of our hemophilia therapies were flat.

Neuroscience

Neuroscience product sales were \$694 million in Q2 2018. VYVANSE product sales increased 7%, due to a U.S. price increase and continued growth in our international markets.

Genetic Diseases

Genetic Diseases product sales increased 6% to \$392 million, driven by favorable foreign exchange rates and increased sales for ELAPRASE primarily in our international markets.

Internal Medicine

Internal Medicine product sales increased 61% to \$233 million, driven by strong demand growth for GATTEX/REVESTIVE and NATPARA/NATPAR, and to a lesser extent, stocking.

Established Brands

Established Brands product sales were \$219 million, declining 36% due to generic competition for LIALDA/MEZAVANT, which began in the second half of 2017.

Ophthalmics

Ophthalmics product sales increased 75% to \$100 million due to strong XIIDRA demand growth.

Oncology

Oncology product sales increased 14% to \$71 million, with growth driven by increased demand for ONIVYDE in international markets.

2. Royalties and other revenues

(in millions)	Revenue	Year on year reported growth
Royalties	\$ 59.7	-47%
Other revenues	51.2	+25%
Royalties and other revenues	\$ 110.9	-28%

Royalties and other revenues decreased 28% primarily due to lower SENSIPAR royalties and the reclassification of ADDERALL XR from royalty revenue to product sales and other changes required under the new revenue accounting standard.

3. Financial details

Cost of sales

(in millions)	Q2 2018	Q2 2017
Cost of sales (U.S. GAAP)	\$ 1,108.3	\$ 1,108.9
Expense related to the unwind of inventory fair value adjustments	(5.8)	(145.0)
Depreciation	(66.1)	(67.0)
Non GAAP cost of sales	\$ 1,036.4	\$ 896.9
U.S. GAAP cost of sales as a percentage of total revenues	28%	30%
Non GAAP cost of sales as a percentage of total revenues	26%	24%

Cost of sales as a percentage of total revenues decreased by 2% to 28%, 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 2% to 26%, primarily due to lower gross margins as Q2 2017 reflected favorability from the timing of changes in the costs to manufacture certain products.

R&D

(in millions)	Q2 2018	Q2 2017
R&D (U.S. GAAP)	\$ 427.6	\$ 542.4
Impairment of IPR&D intangible assets	(10.0)	(20.0)
Costs relating to license arrangements	—	(123.7)
Depreciation	(9.7)	(12.8)
Non GAAP R&D	\$ 407.9	\$ 385.9
U.S. GAAP R&D as a percentage of total revenues	11%	14%
Non GAAP R&D as a percentage of total revenues	10%	10%

R&D decreased by \$115 million, or 21%, as Q2 2017 included significant milestone and upfront payments associated with license arrangements that did not recur in Q2 2018. This resulted in a decrease of R&D as a percentage of total revenues.

Non GAAP R&D increased by \$22 million, or 6%, primarily due to continued investment in late stage and launch programs. Non GAAP R&D as a percentage of total revenues remained consistent with Q2 2017.

SG&A

(in millions)	Q2 2018	Q2 2017
SG&A (U.S. GAAP)	\$ 907.7	\$ 899.1
Legal and litigation costs	—	(7.6)
Depreciation	(59.2)	(40.9)
Non GAAP SG&A	\$ 848.5	\$ 850.6
U.S. GAAP SG&A as a percentage of total revenues	23%	24%
Non GAAP SG&A as a percentage of total revenues	22%	23%

SG&A increased by \$9 million, or 1%, primarily due to increased depreciation resulting from additional assets placed in service, partially offset by benefits from on-going cost reduction initiatives and operating synergies.

Non GAAP SG&A decreased by \$2 million, or less than 1%. Non GAAP SG&A as a percentage of total revenues decreased by 1% due to benefits from on-going cost reduction initiatives and operating synergies.

Amortization of acquired intangible assets

In Q2 2018, Shire recorded amortization of acquired intangible assets of \$458 million (Q2 2017: \$434 million), as the increase was primarily related to the acceleration of CINRYZE amortization with the expected launch of lanadelumab (SHP643), subject to regulatory approval.

Integration and acquisition costs

In Q2 2018, Shire recorded integration and acquisition costs of \$179 million, primarily related to investment banking and third party professional fees related to the proposed Takeda and Servier transactions, integration costs related to Baxalta, and change in fair value of contingent consideration, primarily related to lanadelumab (SHP643), which was acquired from Dyax in 2016.

In Q2 2017, Shire recorded integration and acquisition costs of \$344 million, which included 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 lanadelumab (SHP643), which was acquired from Dyax in 2016.

Other expense, net

(in millions)	Q2 2018	Q2 2017
Other expense, net (U.S. GAAP)	\$ (96.0)	\$ (137.7)
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	0.6	1.7
Gain on sale of non-core investments	—	(13.2)
Fair value adjustment for joint venture net written option	5.0	—
Non GAAP other expense, net	\$ (90.4)	\$ (149.2)

Other expense, net decreased by \$42 million, primarily due to unrealized gains in equity investments and lower interest expense resulting from debt paydown, partially offset by net losses on foreign exchange revaluations on balance sheet exposures.

Non GAAP Other expense, net decreased by \$59 million, primarily due to the reasons discussed above.

Taxation

(in millions)	Q2 2018	Q2 2017
Income tax expense (U.S. GAAP)	\$ (124.4)	\$ (24.3)
Other Non GAAP tax adjustments	(96.9)	(187.6)
Non GAAP income tax expense	\$ (221.3)	\$ (211.9)
U.S. GAAP effective tax rate	17%	9%
Non GAAP effective tax rate	16%	16%

The effective tax rate on U.S. GAAP income in Q2 2018 was 17% (Q2 2017: 9%) and on a Non GAAP basis was 16% (Q2 2017: 16%).

The effective rate in Q2 2018 on U.S. GAAP income from continuing operations has been affected by certain provisions of the U.S. Tax Cuts and Jobs Act (Tax Act) passed in December 2017, which enacts a U.S. federal tax rate of 21% along with anti-deferral provisions, new limitations on certain deductions required under the Tax Act, and reductions in the quantum of and tax benefit associated with U.S. integration costs over the prior year. This increased the effective tax rate for Q2 2018 as compared to Q2 2017.

FINANCIAL INFORMATION

TABLE OF CONTENTS

	Page
Unaudited U.S. GAAP Consolidated Balance Sheets	13
Unaudited U.S. GAAP Consolidated Statements of Operations	14
Unaudited U.S. GAAP Consolidated Statements of Cash Flows	16
Selected Notes to the Unaudited U.S. GAAP Financial Statements	
(1) Earnings per share	18
(2) Analysis of revenues	19
Non GAAP reconciliations	20

Unaudited U.S. GAAP Consolidated Balance Sheets
(in millions, except par value of shares)

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 259.7	\$ 472.4
Restricted cash	35.0	39.4
Accounts receivable, net	3,005.1	3,009.8
Inventories	3,353.3	3,291.5
Held for sale and other current assets	3,135.3	795.3
Total current assets	<u>9,788.4</u>	<u>7,608.4</u>
Non-current assets:		
Investments	527.8	241.1
Property, plant and equipment (PP&E), net	6,426.6	6,635.4
Goodwill	19,043.7	19,831.7
Intangible assets, net	30,110.5	33,046.1
Deferred tax asset	158.3	188.8
Other non-current assets	166.8	205.4
Total assets	<u>\$ 66,222.1</u>	<u>\$ 67,756.9</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,888.5	\$ 4,184.5
Short term borrowings and capital leases	1,192.9	2,788.7
Other current liabilities	1,225.9	908.8
Total current liabilities	<u>6,307.3</u>	<u>7,882.0</u>
Non-current liabilities:		
Long term borrowings and capital leases	16,722.0	16,752.4
Deferred tax liability	4,367.3	4,748.2
Other non-current liabilities	2,065.1	2,197.9
Total liabilities	<u>29,461.7</u>	<u>31,580.5</u>
Equity:		
Common stock of 5p par value; 1,500 shares authorized; and 921.4 shares issued and outstanding (2017: 1,500 shares authorized; and 917.1 shares issued and outstanding)	81.9	81.6
Additional paid-in capital	25,296.4	25,082.2
Treasury stock: 8.1 shares (2017: 8.4 shares)	(275.1)	(283.0)
Accumulated other comprehensive income	727.6	1,375.0
Retained earnings	10,929.6	9,920.6
Total equity	<u>36,760.4</u>	<u>36,176.4</u>
Total liabilities and equity	<u>\$ 66,222.1</u>	<u>\$ 67,756.9</u>

Unaudited U.S. GAAP Consolidated Statements of Operations
(in millions)

	3 months ended June 30,		6 months ended June 30,	
	2018	2017	2018	2017
Revenues:				
Product sales	\$ 3,808.6	\$ 3,591.8	\$ 7,445.7	\$ 7,004.1
Royalties and other revenues	110.9	154.0	239.5	314.0
Total revenues	3,919.5	3,745.8	7,685.2	7,318.1
Costs and expenses:				
Cost of sales	1,108.3	1,108.9	2,240.7	2,435.9
Research and development	427.6	542.4	832.8	921.7
Selling, general and administrative	907.7	899.1	1,712.5	1,788.0
Amortization of acquired intangible assets	457.6	434.1	941.6	798.1
Integration and acquisition costs	179.3	343.7	419.0	459.7
Reorganization costs	8.8	13.6	14.1	19.1
Loss/(gain) on sale of product rights	—	4.8	—	(0.7)
Total operating expenses	3,089.3	3,346.6	6,160.7	6,421.8
Operating income from continuing operations	830.2	399.2	1,524.5	896.3
Interest income	0.9	1.1	3.5	4.2
Interest expense	(125.9)	(141.3)	(252.9)	(283.6)
Other income, net	29.0	2.5	52.2	7.0
Total other expense, net	(96.0)	(137.7)	(197.2)	(272.4)
Income from continuing operations before income taxes and equity in earnings of equity method investees	734.2	261.5	1,327.3	623.9
Income taxes	(124.4)	(24.3)	(167.7)	(31.1)
Equity in earnings of equity method investees, net of taxes	5.7	4.3	6.5	3.5
Income from continuing operations, net of taxes	615.5	241.5	1,166.1	596.3
(Loss)/gain from discontinued operations, net of taxes	—	(1.2)	—	19.0
Net income	\$ 615.5	\$ 240.3	\$ 1,166.1	\$ 615.3

Unaudited U.S. GAAP Consolidated Statements of Operations (continued)

(in millions, except per share amounts)

	3 months ended June 30,		6 months ended June 30,	
	2018	2017	2018	2017
Earnings per Ordinary Share – basic				
Earnings from continuing operations	\$ 0.67	\$ 0.27	\$ 1.28	\$ 0.66
Earnings from discontinued operations	—	—	—	0.02
Earnings per Ordinary Share – basic	\$ 0.67	\$ 0.27	\$ 1.28	\$ 0.68
Earnings per ADS – basic	\$ 2.02	\$ 0.80	\$ 3.84	\$ 2.04
Earnings per Ordinary Share – diluted				
Earnings from continuing operations	\$ 0.67	\$ 0.26	\$ 1.27	\$ 0.65
Earnings from discontinued operations	—	—	—	0.02
Earnings per Ordinary Share – diluted	\$ 0.67	\$ 0.26	\$ 1.27	\$ 0.67
Earnings per ADS – diluted	\$ 2.01	\$ 0.79	\$ 3.82	\$ 2.02
Weighted average number of shares:				
Basic	912.6	906.4	911.0	905.3
Diluted	917.5	912.7	914.8	912.3

Unaudited U.S. GAAP Consolidated Statements of Cash Flows

(in millions)

	3 months ended June 30,		6 months ended June 30,	
	2018	2017	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net income	\$ 615.5	\$ 240.3	\$ 1,166.1	\$ 615.3
Adjustments to reconcile net income to net cash provided by operating activities:				
Depreciation and amortization	592.6	554.8	1,216.8	1,041.7
Share based compensation	45.9	53.7	86.9	106.4
Expense related to the unwind of inventory fair value adjustments	5.8	145.0	39.3	625.4
Change in deferred taxes	(154.5)	(157.8)	(204.9)	(293.3)
Change in fair value of contingent consideration	27.0	151.2	45.9	147.7
Impairment of PP&E and intangible assets	15.8	53.6	153.3	53.6
Other, net	(60.7)	(8.4)	(47.1)	21.6
Changes in operating assets and liabilities:				
Decrease/(increase) in accounts receivable	165.4	(146.2)	(126.3)	(181.5)
(Decrease)/increase in sales deduction accrual	(245.1)	39.6	37.5	57.1
Increase in inventory	(129.6)	(19.8)	(169.8)	(171.6)
Decrease/(increase) in prepayments and other assets	75.2	90.4	(61.5)	104.6
(Decrease)/increase in accounts payable and other liabilities	(13.7)	226.4	(186.3)	(445.1)
Net cash provided by operating activities	939.6	1,222.8	1,949.9	1,681.9
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of PP&E	(183.5)	(178.6)	(361.3)	(391.1)
Proceeds from sale of investments	—	40.6	—	40.6
Other, net	(24.5)	2.0	(35.6)	3.2
Net cash used in investing activities	(208.0)	(136.0)	(396.9)	(347.3)

Unaudited U.S. GAAP Consolidated Statements of Cash Flows (continued)
(in millions)

	3 months ended June 30,		6 months ended June 30,	
	2018	2017	2018	2017
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from revolving line of credit, long term and short term borrowings	2,227.0	710.0	2,650.3	2,111.9
Repayment of revolving line of credit, long term and short term borrowings	(2,822.9)	(1,702.2)	(4,262.3)	(3,527.9)
Payment of dividend	(276.6)	(234.7)	(276.6)	(234.7)
Proceeds from issuance of stock for share-based compensation arrangements	93.2	37.4	133.7	79.5
Other, net	(0.4)	(3.9)	(6.9)	(24.0)
Net cash used in financing activities	(779.7)	(1,193.4)	(1,761.8)	(1,595.2)
Effect of foreign exchange rate changes on cash and cash equivalents	(10.4)	1.4	(8.3)	4.1
Net decrease in cash, cash equivalents, and restricted cash	(58.5)	(105.2)	(217.1)	(256.5)
Cash, cash equivalents, and restricted cash at beginning of period	353.2	403.1	511.8	554.4
Cash, cash equivalents, and restricted cash at end of period	\$ 294.7	\$ 297.9	\$ 294.7	\$ 297.9

Selected Notes to the Unaudited U.S. GAAP Financial Statements

(1) Earnings Per Share (EPS)

(in millions)

	3 months ended June 30,		6 months ended June 30,	
	2018	2017	2018	2017
Income from continuing operations	\$ 615.5	\$ 241.5	\$ 1,166.1	\$ 596.3
(Loss)/gain from discontinued operations	—	(1.2)	—	19.0
Numerator for EPS	\$ 615.5	\$ 240.3	\$ 1,166.1	\$ 615.3
Weighted average number of shares:				
Basic	912.6	906.4	911.0	905.3
Effect of dilutive shares:				
Share based awards to employees	4.9	6.3	3.8	7.0
Diluted	917.5	912.7	914.8	912.3

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

Share based awards to employees	14.4	13.2	15.2	10.3
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Selected Notes to the Unaudited U.S. GAAP Financial Statements

(2) Analysis of revenues

(in millions)

	3 months ended June 30,		6 months ended June 30,	
	2018	2017	2018	2017
Product sales by franchise				
IMMUNOGLOBULIN THERAPIES	\$ 612.1	\$ 510.5	\$ 1,170.0	\$ 1,008.8
HEREDITARY ANGIOEDEMA	365.2	333.9	734.0	700.0
BIO THERAPEUTICS	172.2	172.2	371.4	350.1
Immunology	1,149.5	1,016.6	2,275.4	2,058.9
HEMOPHILIA	746.7	743.9	1,489.5	1,394.3
INHIBITOR THERAPIES	204.3	220.7	414.1	441.2
Hematology	951.0	964.6	1,903.6	1,835.5
VYVANSE	556.0	518.2	1,184.8	1,081.9
ADDERALL XR	79.8	71.4	155.8	136.3
MYDAYIS	16.6	15.7	21.1	15.7
Other Neuroscience	41.3	30.1	76.7	54.8
Neuroscience	693.7	635.4	1,438.4	1,288.7
ELAPRASE	176.5	161.0	294.9	301.6
REPLAGAL	125.6	122.1	249.8	231.8
VPRIV	89.6	87.9	179.5	167.7
Genetic Diseases	391.7	371.0	724.2	701.1
GATTEX/REVESTIVE	133.5	75.3	229.7	144.3
NATPARA/NATPAR	64.8	34.5	109.8	64.2
Other Internal Medicine	34.6	35.3	72.3	68.6
Internal Medicine	232.9	145.1	411.8	277.1
LIALDA/MEZAVANT	105.9	207.8	167.9	382.9
PENTASA	77.5	83.3	149.9	152.4
Other Established Brands	35.1	48.1	74.2	90.7
Established Brands	218.5	339.2	392.0	626.0
Ophthalmics	100.3	57.4	162.4	96.0
Oncology	71.0	62.5	137.9	120.8
Total product sales	3,808.6	3,591.8	7,445.7	7,004.1
Royalties and other revenues				
Royalties	59.7	113.2	130.3	218.3
Other revenues	51.2	40.8	109.2	95.7
Total royalties and other revenues	110.9	154.0	239.5	314.0
Total revenues	\$ 3,919.5	\$ 3,745.8	\$ 7,685.2	\$ 7,318.1

Non GAAP reconciliations

(in millions)

Reconciliation of U.S. GAAP net income to Non GAAP EBITDA and Non GAAP operating income:

	3 months ended June 30,		6 months ended June 30,	
	2018	2017	2018	2017
U.S. GAAP net income	\$ 615.5	\$ 240.3	\$ 1,166.1	\$ 615.3
Add back/(deduct):				
Loss/(gain) from discontinued operations, net of taxes	—	1.2	—	(19.0)
Equity in earnings of equity method investees, net of taxes	(5.7)	(4.3)	(6.5)	(3.5)
Income taxes	124.4	24.3	167.7	31.1
Other expense, net	96.0	137.7	197.2	272.4
U.S. GAAP operating income from continuing operations	830.2	399.2	1,524.5	896.3
Add back/(deduct) Non GAAP adjustments:				
Expense related to the unwind of inventory fair value adjustments	5.8	145.0	39.3	625.4
One-time employee related costs	—	—	—	(4.0)
Impairment of acquired intangible assets	10.0	20.0	10.0	20.0
Costs relating to license arrangements	—	123.7	10.0	123.7
Legal and litigation costs	—	7.6	—	7.6
Amortization of acquired intangible assets	457.6	434.1	941.6	798.1
Integration and acquisition costs	179.3	343.7	419.0	459.7
Reorganization costs	8.8	13.6	14.1	19.1
Loss/(gain) on sale of product rights	—	4.8	—	(0.7)
Depreciation	135.0	120.7	275.2	243.6
Non GAAP EBITDA	1,626.7	1,612.4	3,233.7	3,188.8
Depreciation	(135.0)	(120.7)	(275.2)	(243.6)
Non GAAP operating income	\$ 1,491.7	\$ 1,491.7	\$ 2,958.5	\$ 2,945.2
Net income margin⁽¹⁾	16%	6%	15%	8%
Non GAAP EBITDA margin⁽²⁾	42%	43%	42%	44%

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

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

Reconciliation of U.S. GAAP gross margin to Non GAAP gross margin:

	3 months ended June 30,		6 months ended June 30,	
	2018	2017	2018	2017
U.S. GAAP total revenues	\$ 3,919.5	\$ 3,745.8	\$ 7,685.2	\$ 7,318.1
Cost of sales (U.S. GAAP)	(1,108.3)	(1,108.9)	(2,240.7)	(2,435.9)
U.S. GAAP gross margin⁽¹⁾	2,811.2	2,636.9	5,444.5	4,882.2
Add back Non GAAP adjustments:				
Expense related to the unwind of inventory fair value adjustments	5.8	145.0	39.3	625.4
Depreciation	66.1	67.0	138.8	139.1
Non GAAP gross margin	\$ 2,883.1	\$ 2,848.9	\$ 5,622.6	\$ 5,646.7
U.S. GAAP gross margin⁽¹⁾⁽²⁾	71.7%	70.4%	70.8%	66.7%
Non GAAP gross margin⁽²⁾	73.6%	76.1%	73.2%	77.2%

⁽¹⁾ U.S. GAAP gross margin excludes amortization of acquired intangible assets.

⁽²⁾ U.S. GAAP gross margin as a percentage of total revenues. Non GAAP gross margin as a percentage of total revenues.

Reconciliation of U.S. GAAP net income to Non GAAP net income:

	3 months ended June 30,		6 months ended June 30,	
	2018	2017	2018	2017
U.S. GAAP net income	\$ 615.5	\$ 240.3	\$ 1,166.1	\$ 615.3
Expense related to the unwind of inventory fair value adjustments	5.8	145.0	39.3	625.4
One-time employee related costs	—	—	—	(4.0)
Impairment of acquired intangible assets	10.0	20.0	10.0	20.0
Costs relating to license arrangements	—	123.7	10.0	123.7
Legal and litigation costs	—	7.6	—	7.6
Amortization of acquired intangible assets	457.6	434.1	941.6	798.1
Integration and acquisition costs	179.3	343.7	419.0	459.7
Reorganization costs	8.8	13.6	14.1	19.1
Loss/(gain) on sale of product rights	—	4.8	—	(0.7)
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	0.6	1.7	2.3	3.5
Gain on sale of non-core investments	—	(13.2)	—	(13.2)
Loss/(gain) from discontinued operations	—	1.9	—	(29.9)
Fair value adjustment for joint venture net written option	5.0	—	(3.0)	—
Non GAAP tax adjustments	(96.9)	(188.3)	(240.4)	(387.6)
Non GAAP net income	\$ 1,185.7	\$ 1,134.9	\$ 2,359.0	\$ 2,237.0

Non GAAP reconciliations

(in millions, except per ADS amounts)

Reconciliation of U.S. GAAP diluted earnings per ADS to Non GAAP diluted earnings per ADS:

	3 months ended June 30,		6 months ended June 30,	
	2018	2017	2018	2017
U.S. GAAP diluted earnings per ADS	\$ 2.01	\$ 0.79	\$ 3.82	\$ 2.02
Expense related to the unwind of inventory fair value adjustments	0.02	0.48	0.13	2.06
One-time employee related costs	—	—	—	(0.01)
Impairment of acquired intangible assets	0.03	0.07	0.03	0.07
Costs relating to license arrangements	—	0.41	0.03	0.41
Legal and litigation costs	—	0.02	—	0.02
Amortization of acquired intangible assets	1.50	1.42	3.10	2.62
Integration and acquisition costs	0.59	1.12	1.37	1.51
Reorganization costs	0.03	0.04	0.05	0.06
Loss/(gain) on sale of product rights	—	0.02	—	0.00
Amortization of one-time upfront borrowing costs for Baxalta and Dyax	0.00	0.01	0.01	0.01
Gain on sale of non-core investments	—	(0.04)	—	(0.04)
Loss/(gain) from discontinued operations	—	0.01	—	(0.10)
Fair value adjustment for joint venture net written option	0.02	—	(0.01)	—
Non GAAP tax adjustments	(0.32)	(0.62)	(0.79)	(1.27)
Non GAAP diluted earnings per ADS	\$ 3.88	\$ 3.73	\$ 7.74	\$ 7.36

Reconciliation of U.S. GAAP net cash provided by operating activities to Non GAAP free cash flow:

	3 months ended June 30,		6 months ended June 30,	
	2018	2017	2018	2017
Net cash provided by operating activities	\$ 939.6	\$ 1,222.8	\$ 1,949.9	\$ 1,681.9
Capital expenditures	(183.5)	(178.6)	(361.3)	(391.1)
Payments relating to license arrangements	—	20.0	85.0	20.0
Non GAAP free cash flow	\$ 756.1	\$ 1,064.2	\$ 1,673.6	\$ 1,310.8

Non GAAP net debt comprises:

	June 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 259.7	\$ 472.4
Long term borrowings (excluding capital leases)	(16,383.2)	(16,410.7)
Short term borrowings (excluding capital leases)	(1,184.6)	(2,781.2)
Capital leases	(347.1)	(349.2)
Non GAAP net debt	\$ (17,655.2)	\$ (19,068.7)

Non GAAP reconciliations

(in millions, except per ADS amounts)

Reconciliation of full year 2018 U.S. GAAP diluted earnings per ADS Outlook to Non GAAP diluted earnings per ADS Outlook⁽¹⁾:

	Full Year 2018 Outlook	
	Min	Max
U.S. GAAP diluted earnings per ADS	\$ 7.30	\$ 7.90
Expense related to the unwind of inventory fair value adjustments		0.12
Legal and litigation costs		0.05
Amortization of acquired intangible assets		6.60
Integration and acquisition costs		2.30
Reorganization costs		0.03
Costs relating to license arrangements		0.10
Non GAAP tax adjustments		(1.60)
Non GAAP diluted earnings per ADS	\$ 14.90	\$ 15.50

⁽¹⁾ Does not take into account the sale of the Oncology franchise.

NOTES TO EDITORS

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

Inside Information

This announcement contains inside information.

About Shire

Shire is the global biotechnology leader serving patients with rare diseases and specialized conditions. We seek to push boundaries through discovering and delivering new possibilities for patient communities who often have few or no other champions. Relentlessly on the edge of what's next, we are serial innovators with a diverse pipeline offering fresh thinking and new hope. Serving patients and partnering with healthcare communities in over 100 countries, we strive to be part of the entire patient journey to enable earlier diagnosis, raise standards of care, accelerate access to treatment, and support patients. Our diverse portfolio of therapeutic areas includes Immunology, Hematology, Genetic Diseases, Neuroscience, Internal Medicine, Ophthalmics, and Oncology.

Championing patients is our call to action - it brings the opportunity - and responsibility - to change people's lives.

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, projected revenues, 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 depends on third parties to supply certain inputs and services critical to its operations including certain inputs, services and ingredients critical to its manufacturing processes. 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;
- the nature of producing plasma-based therapies 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;
- failure to comply with laws and regulations governing the sales and marketing of its products could materially impact Shire's revenues and profitability;
- Shire's products and product candidates face substantial competition in the product markets in which it operates, including competition from generics;
- Shire's patented products are subject to significant 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 Shire's revenues, financial condition or results of operations;
- Shire may fail to obtain, maintain, enforce or defend the intellectual property rights required to conduct its business;
- Shire faces intense competition for highly qualified personnel from other companies and organizations;
- failure to successfully execute or attain strategic objectives from Shire's acquisitions and growth strategy 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, could have negative consequences for Shire's business and increase the risk of non-payment by Shire's customers;
- changes in foreign currency exchange rates and interest rates could have a material adverse effect on Shire's operating results and liquidity;
- Shire is subject to evolving and complex tax laws, which may result in additional liabilities that may adversely affect Shire's financial condition or results of operations;
- if a marketed product fails to work effectively or causes adverse side effects, this could result in damage to Shire's reputation, the withdrawal of the product and legal action against Shire;
- 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 faces risks relating to the expected exit of the United Kingdom from the European Union;
- Shire incurred substantial additional indebtedness to finance the Baxalta acquisition, which has increased its borrowing costs and may decrease its business flexibility;

- the potential uncertainty among our employees, customers, suppliers, and other business partners resulting from the announcement by Takeda Pharmaceutical Company Limited on May 8, 2018 of a recommended offer for Shire under the U.K. Takeover Code; 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.

PROFIT FORECASTS

In its FY 2017 results announcement on February 14, 2018 (FY 2017 Announcement), Shire published its full year 2018 outlook for total revenue⁽¹⁾ of \$15.4-\$15.9 billion, GAAP diluted EPS of \$7.30-\$7.90, and non-GAAP diluted EPS of \$14.90-\$15.50 (Full Year 2018 Outlook). Shire also announced "*We are committed to achieving our projected revenue target of \$17-\$18 billion in 2020*" and "*With the already disclosed manufacturing and SG&A cost reduction initiatives, we are on track to achieve mid-forties Non-GAAP EBITDA margin by 2020*" (Mid-Term Outlook).

Certain of the statements on pages 4 and 23 of this announcement include a "profit forecast" for the purposes of Rule 28 of the City Code on Takeovers and Mergers (the "Code") which was first contained in the FY 2017 Announcement.

In accordance with Rule 28.1(c) of the Code, the directors of Shire confirm that: (i) each of the Full Year 2018 Outlook and the Mid-Term Outlook remains valid and has been properly compiled on the basis of the assumptions stated in the FY 2017 Announcement; and (ii) the basis of accounting used for each of the Full Year 2018 Outlook and the Mid-Term Outlook is consistent with Shire's accounting policies.

The Full Year 2018 Outlook and the Mid-Term Outlook do not take into account, and exclude the impact of, the anticipated completion of the sale of the Oncology franchise to Servier S.A.S. (as announced by Shire on April 16, 2018).

⁽¹⁾ Management is providing guidance for total revenue. Total revenue is comprised of total product sales and royalties & other revenues. Pursuant to a change in U.S. GAAP related to accounting for revenue, certain revenue formerly classified as royalties are now recorded as product sales.

NON GAAP MEASURES

This press release contains financial measures not prepared in accordance with U.S. GAAP. These measures are referred to as “Non GAAP” measures and include: *Non GAAP total revenues; Non GAAP operating income; Non GAAP income tax expense; Non GAAP net income; Non GAAP diluted earnings per ADS; Non GAAP effective tax rate; Non GAAP CER; Non GAAP cost of sales; Non GAAP gross margin; Non GAAP R&D; Non GAAP SG&A; Non GAAP other expense, net; Non GAAP tax adjustments; 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 competitors’ 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 differently 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 U.S. GAAP, and Shire’s financial results calculated in accordance with U.S. 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
- Non-controlling interests in consolidated variable interest entities.

Out-license, divestments, reorganizations, and discontinued operations:

- Revenue from up-front and milestone receipts from out-license arrangements;
- 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 U.S. GAAP to Non GAAP measures.

Depreciation, which is included in Cost of sales, R&D, and SG&A costs in our U.S. 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, or receipts, 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 U.S. GAAP is presented on pages 20 to 23.

Non GAAP CER growth is computed by restating 2018 results using average 2017 foreign exchange rates for the relevant period.

Average exchange rates used by Shire for the three months ended June 30, 2018 were \$1.37:£1.00 and \$1.20:€1.00 (2017: \$1.28:£1.00 and \$1.09:€1.00).

A reconciliation of 2020 Non GAAP EBITDA margin to U.S. GAAP net income margin cannot be provided because we are unable to forecast with reasonable certainty many of the items necessary to calculate such comparable GAAP measures, including asset impairments, acquisitions and integration related expenses, divestments, reorganizations and discontinued operations related expenses, legal settlement costs, as well as other unusual or non-recurring gains or losses. These items are uncertain, depend on various factors, and could be material to our results computed in accordance with GAAP. We believe the inherent uncertainties in reconciling Non GAAP measures for periods after 2018 to the most comparable GAAP measures would make the forecasted comparable GAAP measures nearly impossible to predict with reasonable certainty and therefore inherently unreliable.

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