

**Shire plc**

**Half Yearly Report 2015**

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

Statements included herein that are not historical facts 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, that:

- Shire’s products may not be a commercial success;
- product sales from ADDERALL XR and INTUNIV are subject to generic competition;
- the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payers in a timely manner for Shire’s products may affect future revenues, financial condition and results of operations;
- Shire conducts its own manufacturing operations for certain of its products and is reliant on third party contract manufacturers to manufacture other products and to provide goods and services. Some of Shire’s products or ingredients are only available from a single approved source for manufacture. Any disruption to the supply chain for any of Shire’s products may result in Shire being unable to continue marketing or developing a product or may result in Shire being unable to do so on a commercially viable basis for some period of time;
- the manufacture of Shire’s products is subject to extensive oversight by various regulatory agencies. Regulatory approvals or interventions associated with changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, an increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- 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 condition or results of operations;
- 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;
- adverse outcomes in legal matters 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 faces intense competition for highly qualified personnel from other companies and organizations. Shire is undergoing a corporate reorganization and was the subject of an unsuccessful acquisition proposal and the consequent uncertainty could adversely affect Shire’s ability to attract and/or retain the highly skilled personnel needed for Shire to meet its strategic objectives;
- failure to achieve Shire’s strategic objectives with respect to the acquisition of NPS Pharmaceuticals Inc. (“NPS Pharma”) may adversely affect Shire’s financial condition and results of operations; and

other risks and uncertainties detailed from time to time in Shire’s filings with the Securities and Exchange Commission, including those risks outlined in “Item 1A: Risk Factors” in Shire’s Annual Report on Form 10-K for the year ended December 31, 2014.

### TRADE MARKS

All trade marks designated <sup>®</sup> and <sup>™</sup> used in this press release are trade marks of Shire plc or companies within the Shire group except for 3TC<sup>®</sup> and ZEFFIX<sup>®</sup> which are trade marks of GlaxoSmithKline, PENTASA<sup>®</sup> which is a trade mark of FERRING B.V. Corp, LIALDA<sup>®</sup> which is a trade mark of Nogra International Limited, MEZAVANT<sup>®</sup> which is a trade mark of Guiliani International Limited, CALCICHEW<sup>®</sup> which is a trade mark of Takeda, DERMAGRAFT<sup>®</sup> which is a trademark of Organogenesis Inc., VANCOCIN<sup>®</sup> which is a trademark of ANI Pharmaceuticals Inc. and DAYTRANA<sup>®</sup> which is a trade mark of Noven Pharmaceutical Inc. Certain trade marks of Shire plc or companies within the Shire group are set out in Shire’s most recent Annual Report and Accounts for the year ended December 31, 2014.

## Chief Executive Officer's review

We are pleased to enclose our financial results for the six-month period ended June 30, 2015. This Half Yearly Report includes condensed consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP").

### **Flemming Ornskov, M.D., Shire's Chief Executive Officer, commented:**

"During the first half of 2015, we delivered double-digit underlying product sales growth (on a Non GAAP CER<sup>(1)</sup> basis and excluding INTUNIV) amid continued investment in our pipeline and future growth drivers.

Total reported product sales in the first half of 2015 were \$2.9 billion, up 4%, and Non GAAP EBITDA<sup>(2)</sup> reached \$1.4 billion, growing 5%. We are especially pleased by the performance of VYVANSE, with total product sales growing 18% to \$842 million. This includes the market expansion of VYVANSE for adults with ADHD and the launch of the new adult indication for moderate to severe Binge Eating Disorder. The Rare Disease Business Unit continues to be our largest, with product sales of approximately \$1.1 billion. LIALDA has also performed well, gaining market share and generating product sales of \$306 million, up 12%.

During the first half of the year, we further strengthened our focus on rare diseases through the acquisition of NPS Pharma, the largest acquisition in Shire's history. NPS Pharma enabled us to leverage our GI commercial capabilities and global footprint while gaining access to two exciting rare disease assets, GATTEX<sup>®</sup>/REVESTIVE<sup>®</sup> and NATPARA<sup>®</sup>. GATTEX/REVESTIVE is off to a strong start and we are pleased with the early progress of NATPARA. This positive momentum underscores the strength of our M&A capabilities to effectively identify, acquire and integrate assets and deliver value. The NPS Pharma commercial integration has been completed.

Our innovative pipeline saw several key developments in the first half of 2015. We received a Priority Review designation for lifitegrast for Dry Eye Disease and in July 2015 we completed enrolment of the OPUS 3 study for lifitegrast. In addition, we initiated a Phase 3 study for SHP465 ahead of plan and we received favourable FDA feedback on a path forward for a potential Phase 3 study for maribavir. Shire now has the broadest and deepest pipeline in its history."

Flemming Ornskov, M.D.  
Chief Executive Officer

(1) The Non GAAP CER financial measures included within this release is explained on page 59.

(2) Non GAAP earnings before interest, tax, depreciation and amortization ("EBITDA"). A reconciliation to US GAAP net income is provided on page 60.

## Half Yearly Report

### Business overview for the six months to June 30, 2015

The following discussion should be read in conjunction with the unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Half Yearly Report for Shire plc and its subsidiaries (collectively "Shire" or "the Group").

### Significant events in the six months to June 30, 2015 and recent developments

#### Products

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

- The Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") has adopted a positive opinion at its July 2015 meeting recommending marketing authorization approval of INTUNIV (guanfacine) extended release drug product, a non-stimulant indicated as part of a comprehensive treatment programme for ADHD in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.

The CHMP positive opinion will be reviewed by the European Commission ("EC") with the expectation that the EC will then grant a centralized marketing authorization with unified labeling that is valid in the 28 countries that are members of the European Union, as well as European Economic Area members, Iceland, Liechtenstein and Norway.

RESOLOR – for the Symptomatic Treatment of Chronic Constipation in Men

- On May 27, 2015, Shire received the EC decision amending the terms of the RESOLOR Marketing Authorisation to the use of RESOLOR in adults for the symptomatic treatment of chronic constipation for whom laxatives fail to provide adequate relief. In Europe, RESOLOR was initially approved for use in women only, so the new variation extends the use of this treatment to male patients.

VYVANSE – for the treatment of moderate to severe Binge Eating Disorder ("BED") in adults

- Topline results from a 39-week, long-term maintenance of efficacy study (SPD489-346) in adults with moderate to severe BED showed VYVANSE superior to placebo ( $p < .001$ ) on the primary efficacy endpoint of time to relapse of binge eating symptoms. At the conclusion of the trial, patients continuing on VYVANSE had a lower proportion of relapse of 5/136 (3.7%) as compared to patients continuing on placebo 42/131 (32.1%).
- The results of a separate, 12-month open-label safety extension study (SPD489-345) were generally consistent with the safety profile currently outlined in the United States Prescribing information.
- Based on the results of these studies, the Group plans to submit a supplemental New Drug Application by year end to the US Food and Drug Administration ("FDA"). The FDA will evaluate adding this data to the current labeling for VYVANSE.
- On January 30, 2015 Shire launched VYVANSE for the treatment of adults with moderate to severe BED.

VYVANSE – for the treatment of ADHD

- On March 23, 2015 Shire announced VYVANSE was available in a 10mg strength capsule. This new titration dose, which was approved by the FDA on October 30, 2014, is the seventh VYVANSE dosage strength available in addition to the 20mg, 30mg, 40mg, 50mg, 60mg, and 70mg capsule strengths. On April 7, 2015 Health Canada approved the 10mg dose strength for incremental titration adjustments.

NATPARA – for the treatment of hypoparathyroidism

- On January 23, 2015 it was announced that the FDA had approved NATPARA as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. Hypoparathyroidism is a rare endocrine disorder characterized by insufficient levels of parathyroid hormone, or PTH. NATPARA is a bioengineered replica of human PTH. NATPARA was launched on April 1, 2015.

## Pipeline

SHP620 (maribavir) – for the treatment of cytomegalovirus (“CMV”) infection in transplant patients

- In late June 2015, Shire conducted an end of Phase 2 meeting with the FDA and received further clarity on the path forward. Based on this feedback, Shire is considering progressing the program into Phase 3 in 2016.

SHP631 – for the treatment of both the central nervous system (“CNS”) and somatic manifestations in patients with Hunter syndrome (“MPS II”)

- In Q2 2015, a Phase 1 trial of SHP631 (also known as AGT-182) was initiated. SHP631 is an investigational enzyme replacement therapy for the potential treatment of both the CNS and somatic manifestations in patients with Hunter syndrome MPS II.

SHP606 (lifitegrast) – for the treatment of the signs and symptoms of Dry Eye Disease

- Shire has fully enrolled a Phase 3 safety and efficacy study (OPUS-3) in support of potential US and potential international regulatory submissions. OPUS-3 is a multicenter, randomized, double-masked, placebo-controlled, parallel arm study with a 14 day open-label placebo screening run-in period followed by a 12 week randomized, masked treatment period with a primary efficacy endpoint in subjective patient reported symptoms of dry eye disease as measured by the eye dryness score.
- On April 9, 2015 Shire announced that the FDA accepted the New Drug Application for lifitegrast and granted a Priority Review designation. The FDA has set an action date of October 25, 2015, based on the Prescription Drug User Fee Act V.

SHP625 – for the treatment of cholestatic liver disease

- In June 2015, Shire also received preliminary results from an interim analysis of the INDIGO study, a 72 week open label Phase 2 study in PFIC. The interim analysis was based on the first 12 subjects who completed 13 weeks of treatment per protocol. SHP625 was well tolerated but there was no statistically significant reduction in mean serum bile levels from baseline. A change from baseline analysis was planned as there is no placebo treatment arm in this study. The changes from baseline for pruritus did reach statistical significance. 5 of the 20 patients who received the drug experienced sustained decreases from baseline in serum bile acids ranging from 86 to 99% and also experienced marked reductions in pruritus as evidenced by absence of or only mild scratching at their last evaluation in this ongoing study. In this subset of patients where biomarkers of liver damage were elevated at baseline, as assessed by Alanine transaminase and Total Bilirubin, these values were normalized during the study. Shire continues to analyze the totality of the data to determine an appropriate path forward.
- In late May 2015, Shire also received results from the CLARITY trial, a 13 week, double-blind, placebo-controlled Phase 2 study in combination with Ursodeoxycholic Acid in Primary Biliary Cirrhosis. SHP625 did not meet the primary endpoint as measured by change in pruritus or the secondary endpoint in level of liver disease as measured by alkaline phosphatase. However, there was a significant reduction in mean serum bile acid levels versus placebo.
- On April 9, 2015 Shire announced that the small 13-week Phase 2 IMAGO trial of its investigational compound SHP625 did not meet the primary or secondary endpoints in the study of 20 pediatric patients with Alagille syndrome. Given the topline results from the IMAGO study of SHP625 in pediatric patients with Alagille syndrome, we plan to analyze the totality of data to better understand the mixed results we have seen. Data for this and other indications will be important to fully understand the safety and efficacy of SHP625 in patients with cholestatic liver disease.

SHP465 – for the treatment of adults with ADHD

- On April 7, 2015 Shire announced that it had reached an agreement with the FDA on a clear regulatory path for SHP465 (triple-bead mixed amphetamine salts), an investigational oral stimulant medication being evaluated as a potential treatment for ADHD in adults. Shire has begun dosing patients in a Phase 3 study designed to evaluate the efficacy of SHP465 administered as a daily morning dose compared to a placebo in the treatment of children and adolescents (6-17 years of age inclusive) diagnosed with ADHD.

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SHP609 – for the treatment of Hunter syndrome with CNS symptoms

- On January 26, 2015 Shire announced that the FDA has granted Fast Track designation for SHP609 for the treatment of neurocognitive decline associated with Hunter syndrome (mucopolysaccharidosis II).

SHP611 – for the treatment of the late infantile form of MLD

- SHP611 is in development as recombinant human arylsulfatase A (rASA) delivered intrathecally every other week for the treatment of the late infantile form of MLD. This product has been granted orphan drug designation in the US and the EU. The Group initiated a 24 patient Phase 1/2 clinical trial in August 2012. The primary endpoint of this trial is to determine the safety of ascending doses (10mg, 30mg, and 100 mg) of rASA over 40 weeks. Secondary and exploratory endpoints focused on efficacy and include decline in motor function as defined by change in baseline Gross Motor Function Measure (GMFM-88). Based upon interim data for the first 18 patients, SHP611 was safe and well tolerated at all doses. In addition, while not statistically significant and despite a decline in GMFM-88 score across all doses, the 100mg dose caused a slower decline over the 40 week study period compared to the other two treatment groups, most notably for those patients with GMFM-88 > 40-50 at baseline. Analysis of other exploratory efficacy measures were also encouraging. We will continue to analyze these interim results and determine an optimal path forward in this development program.

### Other developments

Board and Committee Changes

- On June 11, 2015 Shire announced the appointment of Olivier Bohuon to the Shire Board of Directors as a Non-Executive Director. Olivier will also be a member of the Science & Technology Committee of the Shire Board. Both appointments were effective from July 1, 2015.

Meritage acquisition

- On February 24, 2015 Shire announced that it had acquired Meritage Pharma, Inc., a privately-held Group, for an upfront payment of \$75 million and additional contingent payments based on the achievement of development and regulatory milestones. With the acquisition, Shire has acquired the global rights to Meritage's Phase 3-ready compound, Oral Budesonide Suspension (SHP621), for the treatment of adolescents and adults with eosinophilic esophagitis, a rare, chronic inflammatory GI disease. This acquisition further enhances Shire's late-stage pipeline and leverages the Group's rare disease and GI commercial infrastructure and expertise.

NPS Pharma acquisition

- On February 21, 2015 Shire completed the acquisition of NPS Pharma. Shire plans to accelerate the growth of NPS Pharma's innovative portfolio through its market expertise in gastrointestinal ("GI") disorders, core capabilities in rare disease patient management, and global footprint. The integration is progressing according to plan.

### Legal Proceedings

See note 15 Commitments and contingencies of this Half Yearly Report for details of Shire's legal proceedings.

### Dividend

- In respect of the six months ended June 30, 2015 the Board resolved to pay an interim dividend of 4.21 US cents per Ordinary Share (2014: 3.83 US cents per Ordinary Share).

Dividend payments will be made in Pounds Sterling to holders of Ordinary Shares and in US Dollars to holders of ADSs. A dividend of 2.69<sup>(1)</sup> pence per Ordinary Share (an increase of 20% compared to 2014: 2.24 pence) and 12.63 US cents per ADS (an increase of 10% compared to 2014: 11.49 US cents) will be paid on October 2, 2015 to shareholders on the register as at the close of business on September 4, 2015.

(1) Translated using a GBP:USD exchange rate of 1.5631.

## Research and development

### *Products in registration as of June 30, 2015*

#### **INTUNIV for the treatment of ADHD in the EU**

The CHMP of the EMA has adopted a positive opinion at its July 2015 meeting recommending marketing authorization approval of INTUNIV (guanfacine) extended release drug product, a non-stimulant indicated as part of a comprehensive treatment programme for ADHD in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.

The CHMP positive opinion will be reviewed by the EC with the expectation that the EC will then grant a centralized marketing authorization with unified labeling that is valid in the 28 countries that are members of the European Union, as well as European Economic Area members, Iceland, Liechtenstein and Norway.

#### **SHP606 (lifitegrast) for the treatment of DED**

On April 9, 2015 Shire announced that the FDA had accepted for filing the NDA for lifitegrast and had granted a Priority Review designation. The FDA is expected to provide a decision on October 25, 2015, based on the Prescription Drug User Fee Act V action date. In parallel to the NDA submission, Shire has fully enrolled a Phase 3 safety and efficacy study (OPUS-3) in support of potential US and potential international regulatory submissions. OPUS-3 is a multicenter, randomized, double-masked, placebo-controlled, parallel arm study with a 14 day open-label placebo screening run-in period followed by a 12 week randomized, masked treatment period with a primary efficacy endpoint in subjective patient reported symptoms of dry eye disease, as measured by the eye dryness score.

On April 30, 2014 Shire announced top-line results from the prospective, randomized, double-masked, placebo-controlled SONATA trial which indicated no ocular or drug-related serious adverse events. The safety data indicated in the SONATA trial was entirely consistent with that observed in the Phase 2, OPUS-1 and OPUS-2 studies for lifitegrast.

#### **NATPAR for the treatment of HPT**

NATPAR (NATPARA in the US) is currently under review in Europe as an adjunct to calcium and vitamin D to control hypocalcemia in patients with HPT.

### *Products in clinical development as of June 30, 2015*

#### **Phase 3 and Phase 3-ready**

#### **SHP465 for the treatment of ADHD in adults**

Shire's NDA for SHP465 was previously submitted in 2006 to support the use of SHP465 as a longer-acting, once-daily treatment for ADHD in adults. With the growing adult ADHD population there is now a larger patient population and Shire expects a greater commercial need for this type of product than in 2006. SHP465 (mixed salts of a single entity amphetamine) capsules provide an extended-release of amphetamines to provide coverage of ADHD symptoms for adults throughout the day. On April 7, 2015 Shire announced that it had reached an agreement with the FDA on a clear regulatory path for SHP465. Shire has begun dosing patients in a Phase 3 study designed to evaluate the efficacy of SHP465 administered as a daily morning dose compared to a placebo in the treatment of children and adolescents (6-17 years of age inclusive) diagnosed with ADHD.

#### **SHP621 OBS, for the treatment of adolescents and adults with Eosinophilic Esophagitis ("EoE")**

With the Meritage acquisition, Shire has acquired the global rights to Meritage's Phase 3-ready compound, OBS, for the treatment of adolescents and adults with EoE, a rare, chronic inflammatory GI disease. EoE is a chronic disease that is increasingly being diagnosed in children and adults, with an estimated prevalence in the U.S. of ~181,000. It is characterized by inflammation and accumulation of a specific type of immune cell, called an eosinophil, in the esophagus. EoE patients may have persistent or relapsing symptoms related to esophageal dysfunction, which include dysphagia (difficulty swallowing) and food impaction.

OBS is a proprietary viscous oral formulation of budesonide that is designed to coat the esophagus where the drug can act locally. Budesonide is the active pharmaceutical ingredient in several products approved by the FDA, including products for the treatment of asthma, allergic rhinitis, ulcerative colitis and Crohn's disease. Budesonide is a corticosteroid and has an established safety profile in those diseases. The FDA has granted orphan drug designation to OBS for the treatment of patients with EoE.



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### **FIRAZYR for the treatment of ACE inhibitor-induced Angioedema (“ACE-I AE”)**

A Phase 3 clinical trial to assess the efficacy of FIRAZYR for the treatment of ACE-I AE was initiated in the fourth quarter of 2013 and is ongoing.

### **FIRAZYR for the treatment of Hereditary Angioedema (“HAE”) in Japan**

Shire plans to initiate a Phase 3 trial to evaluate the efficacy and safety of FIRAZYR for the treatment of HAE in Japanese patients in 2015.

### **SHP555 (prucalopride; marketed as RESOLOR in the EU) for the treatment of chronic constipation in the US**

On January 10, 2012 Shire announced that it had acquired the rights to develop and market prucalopride in the US in an agreement with Janssen Pharmaceutica N.V. Discussions have been conducted with the FDA and an NDA submission pathway has been agreed. Planning is underway to confirm Phase 3 program activities and timelines.

### **INTUNIV for the treatment of ADHD in Japan**

Under a collaboration agreement, Shionogi and Shire will co-develop and sell treatments for ADHD in Japan, including INTUNIV. A Phase 3 clinical program to evaluate the efficacy and safety of INTUNIV in Japanese patients aged 6 to 17 was initiated in the second quarter of 2013 and is ongoing.

### **SHP616 (CINRYZE) for routine prophylaxis against HAE attacks in adolescent and adult patients in Japan**

CINRYZE is indicated in the US for prophylaxis and in the EU for both prophylaxis and acute treatment of angioedema attacks in adolescent and adult patients with HAE. Based on feedback from the Pharmaceutical and Medical Devices Agency (“PMDA”), a Clinical Trial Notification (“CTN”) was resubmitted and approved on October 2, 2014.

### **Phase 2**

#### **LDX(1) for the treatment of ADHD in Japan**

Under a collaboration agreement, Shionogi and Shire will co-develop and sell ADHD products in Japan, including LDX. A Phase 2 clinical program to evaluate the efficacy and safety of LDX in Japanese patients aged 6 to 17 was initiated in the second quarter of 2013 and is ongoing.

(1) Currently marketed as VYVANSE in the US and ELVANSE in certain countries in the EU for the treatment of ADHD.

### **SHP607 for the prevention of Retinopathy of Prematurity (“ROP”)**

SHP607 is in development as a protein replacement therapy for the preventative treatment of ROP, a rare eye disorder associated with premature birth. In December 2014 Shire received notification that SHP607 was granted Fast Track designation by the FDA. In addition, this product has been granted orphan drug designation in both the US and EU. A Phase 2 clinical trial is currently ongoing.

### **SHP609 for the treatment of Hunter syndrome with CNS symptoms**

SHP609 is in development as an enzyme replacement therapy (“ERT”) delivered intrathecally for Hunter syndrome patients with cognitive impairment. In January 2015 the FDA granted SHP609 Fast Track designation. In addition, this product has been granted orphan designation in the US. The Group initiated a pivotal Phase 2/3 clinical trial in the fourth quarter of 2013 which is ongoing.

### **SHP610 for Sanfilippo A syndrome (Mucopolysaccharidosis IIIA)**

SHP610 is in development as an ERT delivered intrathecally for the treatment of Sanfilippo A syndrome, a Lysosomal Storage Disorder. The Group initiated a Phase 1/2 clinical trial in August 2010 which has now completed. Shire initiated a Phase 2b clinical trial for SHP610, which is designed to establish clinical proof of concept. The product has been granted orphan drug designation in the US and in the EU.

### **SHP620 (maribavir) for the treatment of CMV infection in transplant patients**

SHP620 was acquired as part of the acquisition of ViroPharma. Shire has completed two Phase 2 studies in transplant recipients. The first trial was in first-line treatment of asymptomatic CMV viremia in transplant recipients and the results of this study showed that maribavir, at all doses, was at least as effective as valganciclovir in the reduction of circulating CMV to below the limits of assay detection (undetectable plasma CMV). The second study recently completed was for the treatment of resistant/refractory CMV infection/disease in transplant recipients. The purpose of this study was to determine whether maribavir is efficacious and safe in patients with disease which is resistant or

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refractory to the standard of care CMV therapy (e.g., valganciclovir, foscarnet). This study also showed that maribavir, at all doses, was effective at lowering CMV to below the limits of assay detection. Approximately two-thirds of patients across the maribavir treatment groups achieved undetectable plasma CMV DNA (viral load) within 6 weeks. This product has been granted orphan drug designation in both the US and EU. In late June, 2015 Shire conducted an end of Phase 2 meeting with the FDA and received further clarity on the path forward. Based upon this feedback, Shire is considering progressing the program into Phase 3 in 2016.

### **SHP625 for the treatment of cholestatic liver disease**

SHP625 was acquired as part of the recent acquisition of Lumena. Shire is currently conducting Phase 2 studies in the following indications: ALGS, PFIC, PBC, and Primary Sclerosing Cholangitis. This product has been granted orphan drug designation both in the US and EU.

On April 9, 2015 Shire announced that the 13-week Phase 2 IMAGO trial of SHP625 did not meet the primary or secondary endpoints in the study of 20 pediatric patients with ALGS. Mean serum bile acid levels and pruritus at the end of the study were lower in both SHP625 and placebo treated groups as compared to baseline. However, in a post-hoc analysis, a positive correlation between percent changes from baseline in serum bile acid levels and pruritus was observed in the SHP625 treated group.

In late May 2015, Shire also received results from the CLARITY study, a 13 week, doubled blind, placebo-controlled Phase 2 study in combination with UDCA in PBC. SHP625 did not meet the primary endpoint as measured by change in pruritus or the secondary endpoint in level of liver disease as measured by the ALP. However, there was a significant reduction in mean serum bile acid levels versus placebo.

In June 2015, Shire received preliminary results from an interim analysis of the INDIGO study, a 72 week open label Phase 2 study in PFIC. The interim analysis was based on the first 12 subjects who completed 13 weeks of treatment per protocol. SHP625 was well tolerated but there was no statistically significant reduction in mean serum bile levels from baseline. A change from baseline analysis was planned as there is no placebo treatment arm in this study. The changes from baseline for pruritus did reach statistical significance. 5 of the 20 patients who received the drug experienced sustained decreases from baseline in serum bile acids ranging from 86 to 99% and also experienced marked reductions in pruritus as evidenced by absence of or only mild scratching at their last evaluation in this ongoing study. In this subset of patients where biomarkers of liver damage were elevated at baseline, as assessed by ALT and Total Bilirubin, these values were normalized during the study. Shire continues to analyze the totality of the data to determine an appropriate path forward.

### **SHP616 (CINRYZE) for the treatment of Acute Antibody Mediated Rejection (“AMR”)**

A Phase 2 study for the treatment of AMR with SHP616 was completed in 18 patients. Shire has received FDA and EMA feedback and submitted an investigational new drug application (“IND”) in the second quarter of 2015. Shire plans to initiate a Phase 2/3 study in the second half of 2015.

#### **Phase 1**

### **SHP611 for the treatment of Metachromatic Leukodystrophy (“MLD”)**

SHP611 is in development as recombinant human arylsulfatase A (“rASA”) delivered intrathecally every other week for the treatment of the late infantile form of MLD. This product has been granted orphan drug designation in the US and the EU. The Group initiated a 24 patient Phase 1/2 clinical trial in August 2012. The primary endpoint of this trial is to determine the safety of ascending doses of rASA over 40 weeks. The secondary endpoint focuses on decline in motor function as defined by change in baseline Gross Motor Function Measure (“GMFM-88”). Exploratory endpoints include change from baseline in cerebrospinal fluid sulfatide levels and change from baseline in the total MLD severity score based on brain Magnetic Resonance Imaging (“MRI”). The trial is currently ongoing, but top line interim results were available in late April. Based upon interim data for the first 18 patients, SHP611 was safe and well tolerated at all doses. In addition, while not statistically significant and despite a decline in GMFM-88 score across all doses, the highest dose caused a slower decline over the 40 week study period compared to the lower dose treatment groups. The higher dose group also showed encouraging data in reduced MLD MRI score and reductions of CSF sulfatide. Shire will continue to analyze these interim results and determine an optimal path forward in this development program.

### **SHP616 (CINRYZE) life cycle management and new uses**

Shire is pursuing a subcutaneous formulation of CINRYZE for routine prophylaxis against HAE attacks in adolescent and adult patients. In addition to initiating a Phase 2/3 study (discussed above), Shire is considering pursuing development in Neuromyelitis Optica (“NMO”). Shire received feedback from the FDA in the second quarter of 2015 on NMO and is in the process of determining an optimal path forward. After further investigation, Shire has decided not to pursue development in Paroxysmal Nocturnal Hemoglobinuria (“PNH”).

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### **SHP622 for the treatment of Friedreich's Ataxia ("FA")**

SHP622 is in development for the treatment of Friedreich's Ataxia and was acquired as part of the acquisition of ViroPharma. This product is a naturally occurring small molecular weight drug compound that prevents oxidative stress OX1 (indole-3-propionic acid) by a combination of hydroxyl radical scavenging activity and metal chelation. Phase 1 studies in healthy adults were completed in 2010. The drug was found to be generally well tolerated, and the pharmacokinetics revealed that the drug was rapidly absorbed and distributed in the body after oral administration. A Phase 1b trial of SHP622 in adults with FA is ongoing.

### **SHP626 for the treatment of nonalcoholic steatohepatitis ("NASH")**

SHP626 was acquired as part of the acquisition of Lumena and is in development for the treatment of NASH, a common and often "silent" liver disease characterized by fat deposits in the liver and inflammation which can progress to significant fibrosis. A US IND was approved by the FDA in the fourth quarter of 2014, and a Phase 1b multiple dose trial is ongoing.

### **SHP627 for the treatment of focal segmental glomerulosclerosis ("FSGS")**

On July 4, 2014 Shire completed its acquisition of Fibrotech, an Australian biopharmaceutical company developing a new class of orally available drugs with a novel mechanism of action which has the potential to address both the inflammatory and fibrotic components of disease processes. SHP627 has completed a Phase 1a study in healthy volunteers and is currently in a Phase 1b study in patients with diabetic nephropathy. The first Phase 2 study is expected to be initiated in FSGS patients in 2017.

### **SHP631 for the treatment of both the CNS and somatic manifestations in patients with MPS II**

On July 23, 2014, Shire announced a worldwide licensing and collaboration agreement with ArmaGen for SHP631 (also known as AGT-182). SHP631 is an investigational enzyme replacement therapy for the potential treatment of both the central nervous system and somatic manifestations in patients with MPS II. SHP631 is designed to take advantage of the body's natural system for transporting products across the blood brain barrier by using the same receptor that delivers insulin to the brain. SHP631 has received orphan drug designation from both the FDA and the EMA. In the second quarter of 2015, ArmaGen initiated a Phase 1 sequential, open-label, dose escalation, multi-dose study in adults with Hunter syndrome. At least two dose levels, assuming tolerability, are planned sequentially, and the trial is expected to deliver information on the possible effect of SHP631 on CSF levels of glycosaminoglycan substrate, which will be important in determining the next steps in clinical development.

### **Other development projects**

A number of additional early development projects, focused on Rare Diseases, are underway in various stages of pre-clinical development.

## Half Yearly Report

### Going Concern

As stated in Note 1 to the consolidated financial statements, the Directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future. Thus, they continue to adopt the going concern basis of accounting in preparing the half-yearly report.

## Half Yearly Report



### Results of operations for the six months to June 30, 2015 and June 30, 2014

The financial information contained within the Half Yearly Report has been prepared under US GAAP, being the accounting principles under which the Group will prepare or prepared its annual financial statements for the years ended December 31, 2015 and 2014.

#### Total revenues

The following table provides an analysis of the Group's total revenues by source:

	6 months to June 30, 2015 \$'M	6 months to June 30, 2014 \$'M	change %
Product sales	2,899.4	2,777.7	+4
Royalties	141.9	61.5	+131
Other revenues	4.7	9.7	-52
Total	3,046.0	2,848.9	+7

## Product sales

The following table provides an analysis of the Group's key product sales:

	6 months to June 30, 2015 \$'M	6 months to June 30, 2014 \$'M	Product sales growth %	Non-GAAP CER Growth <sup>(4)</sup> %	US prescription growth <sup>(1)</sup> %	Exit market share <sup>(1)</sup> %
<b>Net product sales:</b>						
VYVANSE	841.6	710.7	+18	+20	+7	+16
LIALDA/MEZAVANT	306.4	272.5	+12	+15	+11	+35
ELAPRASE	271.5	280.7	-3	+8	n/a <sup>(2)</sup>	n/a <sup>(2)</sup>
CINRYZE	286.9	215.5	+33	+35	n/a <sup>(2)</sup>	n/a <sup>(2)</sup>
REPLAGAL	214.4	244.8	-12	+1	n/a <sup>(3)</sup>	n/a <sup>(3)</sup>
FIRAZYR	196.6	163.9	+20	+23	n/a <sup>(2)</sup>	n/a <sup>(2)</sup>
ADDERALL XR	181.7	184.9	-2	-1	+14	+5
VPRIV	171.1	176.6	-3	+5	n/a <sup>(2)</sup>	n/a <sup>(2)</sup>
PENTASA	145.0	135.5	+7	+7	-7	+12
FOSRENOL	89.2	88.1	+1	+9	-11	+3
GATTEX/REVESTIVE	52.2	-	n/a	n/a	n/a <sup>(2)</sup>	n/a <sup>(2)</sup>
XAGRID	48.1	55.0	-13	+3	n/a <sup>(2)</sup>	n/a <sup>(2)</sup>
INTUNIV	26.9	182.3	-85	-85	-64	+1
NATPARA	5.9	-	n/a	n/a	n/a <sup>(2)</sup>	n/a <sup>(2)</sup>
Other product sales	61.9	67.2	-8	+3	n/a	n/a
<b>Total product sales</b>	<b>2,899.4</b>	<b>2,777.7</b>	<b>+4</b>			

(1) Data provided by IMS Health National Prescription Audit ("IMS NPA") relates solely to US-based prescriptions. Exit market share represents the average monthly market share in the month ended June 30, 2015.

(2) IMS NPA Data not available.

(3) Not sold in the US in the six months to June 30, 2015.

(4) The Group's management analyzes product sales and revenue growth for certain products sold in markets outside of the US on a constant exchange rate ("CER") basis, so that product sales and revenue growth can be considered excluding movements in foreign exchange rates. Product sales and revenue growth on a CER basis is a Non GAAP financial measure ("Non GAAP CER"), computed by comparing 2015 product sales and revenues restated using 2014 average foreign exchange rates to 2014 actual product sales and revenues. Average exchange rates for the six months to June 30, 2015 were \$1.53:£1.00 and \$1.13:€1.00 (2014: \$1.67:£1.00 and \$1.37:€1.00).

## Half Yearly Report

### **VYVANSE – ADHD**

VYVANSE product sales grew strongly in the six months to June 30, 2015 (up 18% compared to the same period in 2014) primarily due to a price increase<sup>(1)</sup> taken since 2014, higher prescription demand, stocking in the first half of 2015 and to a slightly lesser extent growth in international sales.

Litigation proceedings regarding VYVANSE are ongoing. Further information about this litigation can be found in note 15 of this Half Yearly Report.

### **LIALDA/MEZAVANT – Ulcerative Colitis**

Product sales for LIALDA/MEZAVANT in the six months to June 30, 2015 were up 12% (up 15% on a Non GAAP CER basis), primarily due to higher US prescription demand and the effect of a price increase<sup>(1)</sup> taken since 2014. These factors were partially offset by higher sales deductions as a percentage of product sales and the negative impact of foreign exchange movements.

Litigation proceedings regarding LIALDA are ongoing. Further information about this litigation can be found in note 15 of this Half Yearly Report.

### **ELAPRASE – Hunter syndrome**

ELAPRASE product sales in the six months to June 30, 2015 were down 3% compared to the same period in 2014 (up 8% on a Non GAAP CER basis). Continued growth in the number of treated patients and the benefit of a price increase<sup>(1)</sup> taken since 2014 was more than offset by the negative impact of foreign exchange movements.

Litigation proceedings regarding ELAPRASE are ongoing. Further information about this litigation can be found in note 15 of this Half Yearly Report.

### **CINRYZE –prophylactic treatment of HAE**

Shire acquired CINRYZE through its acquisition of ViroPharma in the first quarter of 2014. CINRYZE product sales in the six months to June 30, 2015 were up 33% compared to the same period in 2014 (17% on a proforma basis<sup>(2)</sup>) primarily due to continued growth in the number of patients on therapy and to a lesser extent the benefit of a price increase<sup>(1)</sup> taken since 2014.

### **REPLAGAL – Fabry disease**

REPLAGAL sales were down 12% (up 1% on a Non GAAP CER basis) in the six months to June 30, 2015 compared to the same period in 2014 driven primarily by the negative impact of foreign exchange movements.

### **FIRAZYR – acute treatment of HAE**

FIRAZYR product sales grew strongly up 20% (up 23% on a Non GAAP CER basis) compared to the same period in 2014. This was primarily due to growth in patients on therapy and to a lesser extent the effect of a price increase<sup>(1)</sup> taken since 2014. These factors were partially offset by the negative impact of foreign exchange movements.

### **ADDERALL XR – ADHD**

ADDERALL XR product sales decreased (down 2%) in the six months to June 30, 2015, as increased prescription demand (up 14%) was more than offset by the effect of higher sales deductions as a percentage of product sales.

### **VPRIV – Gaucher disease**

VPRIV product sales in the six months to June 30, 2015 were down 3% (up 5% on a Non GAAP CER basis), reflecting the negative impact of foreign exchange movements partially offset by higher unit sales from an increase in the number of patients on therapy.

### **PENTASA – Ulcerative Colitis**

PENTASA product sales increased in the six months to June 30, 2015 (up 7%) driven by price increases<sup>(1)</sup> taken since 2014, partially offset by a decrease in US prescription demand and higher sales deductions as a percentage of product sales.

### **GATTEX/REVESTIVE – Short Bowel Syndrome (“SBS”)**

Shire acquired GATTEX/REVESTIVE through its acquisition of NPS Pharma on February 21, 2015, and has recorded sales of \$52 million (up 60% on a proforma basis<sup>(3)</sup>) for the period subsequent to acquisition.

## INTUNIV – ADHD

INTUNIV product sales were down 85% in the six months to June 30, 2015 reflecting the impact of generic competitors in December 2014 and June 2015, which resulted in lower prescription demand and significantly higher sales deductions as a percentage of product sales.

## NATPARA – Hypoparathyroidism

Shire made NATPARA available on April 1, 2015, after acquiring the product through its acquisition of NPS Pharma. In the first half of 2015 sales of \$6 million were recorded.

(1) The actual net effect of price increases on current period net sales compared to the comparative period is difficult to quantify due to the various managed care rebates, Medicaid discounts, other discount programs in which the Group participates and fee for service agreements with wholesalers customers.

(2) 2014 Proforma revenues include revenues recorded by ViroPharma, prior to the acquisition of ViroPharma by Shire on January 24th 2014.

(3) Proforma revenues include revenues recorded by NPS Pharma, prior to the acquisition of NPS Pharma by Shire on February 21st 2015.

## Royalties

The following table provides an analysis of Shire's royalty income:

	6 months to June 30, 2015 \$'M	6 months to June 30, 2014 \$'M	Change %
SENSIPAR	45.2	-	n/a
INTUNIV	27.8	-	n/a
FOSRENOL	19.2	22.2	-14
3TC and ZEFFIX	18.0	15.8	+14
ADDERALL XR	15.1	13.5	+12
Other	16.6	10.0	+66
Total royalties	141.9	61.5	+131

Royalties in the first half of 2015 are higher than the first half of 2014 due to the inclusion of royalty income receivable from Amgen for SENSIPAR following the acquisition of NPS Pharma by Shire, and the inclusion of royalties receivable from Actavis on its generic sales of INTUNIV.

## Cost of product sales

Cost of product sales was \$455.8 million for the six months to June 30, 2015 (16% of product sales), down from \$506.5 million in the corresponding period in 2014 (18% of product sales). Cost of product sales as a percentage of product sales was two percentage points lower compared to the same period in 2014 due to lower charges in relation to the unwind of the fair value adjustment on inventories acquired in business combinations.

For the six months to June 30, 2015 cost of product sales included depreciation of \$24.8 million (2014: \$28.0 million).

## R&D

R&D expenditure increased to \$969.6 million for the six months to June 30, 2015 (33% of product sales), compared to \$597.4 million in the corresponding period in 2014 (22% of product sales). R&D expenditure in 2015 includes impairment charges of \$346.6 million relating to the SHP625 IPR&D intangible asset, due to a lower probability of regulatory approval following trial results, and \$176.7 million relating to the SHP608 IPR&D intangible asset, following preclinical toxicity findings. In 2014 R&D expenditure included impairment charges of \$166.0 million related to the SHP602 IPR&D intangible asset, following the decision to place the program on clinical hold and \$22.0 million related to the SHP613 IPR&D intangible asset, following the decision to discontinue further development of the asset. Excluding these impairment charges, R&D expenditure in the six months to June 30, 2015 increased by 9% or by \$36.9 million, due to the first time inclusion of NPS Pharma's R&D costs and continued investment in existing pipeline programs.

R&D in the six months to June 30, 2015 included depreciation of \$11.7 million (2014: \$11.6 million).



## Half Yearly Report

### SG&A

SG&A expenditure increased to \$1,133.9 million (39% of product sales) for the six months to June 30, 2015 from \$926.5 million (33% of product sales) in the corresponding period in 2014 due to increased investment behind launches, including the successful launch of VYVANSE for the treatment of moderate to severe BED in adults, the first time inclusion of NPS Pharma's SG&A costs from February 21, 2015, and higher intangible asset amortization.

For the six months to June 30, 2015 SG&A included depreciation of \$35.7 million (2014: \$41.9 million) and amortization of \$219.6 million (2014: \$119.0 million).

### Gain on sale of product rights

For the six months to June 30, 2015 Shire recorded a net gain on sale of product rights of \$12.3 million (2014: \$40.2 million). The gain in 2015 primarily relates to the re-measurement of contingent consideration receivable from the divestment of DAYTRANA. The gain in 2014 related to the sale of CALCICHEW trademarks to Takeda and the re-measurement of contingent consideration receivables from the divestment of DAYTRANA.

### Reorganization costs

For the six months to June 30, 2015 Shire recorded reorganization costs of \$28.5 million (2014: \$95.2 million), related to the One Shire reorganization.

### Integration and acquisition costs

For the six months to June 30, 2015 Shire recorded a net credit for integration and acquisition costs of \$136.7 million (2014: a charge of \$118.7 million), comprising costs of \$119.0 million primarily related to the acquisition and integration of NPS Pharma offset by a net credit of \$255.7 million relating to the change in fair values of contingent consideration liabilities. The change in fair value of contingent consideration liabilities in the six months to June 30, 2015 relates principally to SHP625 (acquired with Lumena) and SHP608 (acquired with Lotus Tissue Repair).

In the six months to June 30, 2014 the charge comprised costs of \$97.3 million relating to the acquisition and integration of ViroPharma and a net charge of \$21.4 million relating to the change in fair values of contingent liabilities.

### Interest expense

For the six months to June 30, 2015 Shire incurred interest expense of \$20.9 million (2014: \$18.9 million), primarily related to interest and amortization of financing fees incurred on borrowings to fund the NPS Pharma acquisition. Interest expense in 2014 principally related to interest and amortization of issue costs incurred on borrowings to fund the ViroPharma acquisition.

### Taxation

The effective rate of tax for the six months to June 30, 2015 was 2% (2014: -19%).

The effective rate of tax for the six months to June 30, 2015 is low primarily due to the reduction in deferred tax liabilities in relation to the impairment of IPR&D intangible assets, the re-measurement of uncertain tax positions relating to ongoing tax audits and the release of certain valuation allowances all recognized during the first half.

The effective rate of tax in the six months to June 30, 2014 was negative primarily due to the recognition of a net tax credit in the first half of 2014 in relation to the settlement of tax positions with the Canadian revenue authorities.

### Discontinued operations

The loss from discontinued operations for the six months to June 30, 2015 was \$7.0 million net of tax (2014: \$27.9 million) relating to costs associated with the divestment of the DERMAGRAFT business.

## Half Yearly Report

### Financial condition at June 30, 2015 and December 31, 2014

#### **Cash & cash equivalents**

Cash and cash equivalents decreased by \$2,918.4 million to \$64.0 million at June 30, 2015 (December 31, 2014: \$2,982.4 million), primarily due to the use of existing cash and cash equivalents to fund the acquisitions of NPS Pharma and Meritage.

#### **Accounts receivable, net**

Accounts receivable, net increased by \$64.1 million to \$1,099.2 million at June 30, 2015 (December 31, 2014: \$1,035.1 million), primarily due to the inclusion of NPS Pharma's accounts receivable and an increase in revenue. Days sales outstanding increased to 46 days (December 31, 2014: 43 days).

#### **Inventories**

Inventories increased by \$88.0 million to \$632.8 million at June 30, 2015 (December 31, 2014: \$544.8 million), primarily due to the inventories acquired as part of the acquisition of NPS Pharma.

#### **Goodwill**

Goodwill increased by \$1,698.3 million to \$4,173.2 million at June 30, 2015 (December 31, 2014: \$2,474.9 million), principally due to the acquisitions of NPS Pharma and Meritage.

#### **Other intangible assets, net**

Other intangible assets increased by \$4,376.0 million to \$9,310.4 million at June 30, 2015 (December 31, 2014: \$4,934.4 million), principally due to the intangible assets acquired with NPS Pharma and Meritage, offset by IPR&D intangible asset impairment charges and intangible asset amortization.

#### **Short term borrowings**

Short term borrowings increased by \$1,379.9 million to \$2,229.5 million at June 30, 2015 (December 31, 2014: \$850.0 million), reflecting the utilization of short term debt facilities to partially fund the acquisition of NPS Pharma and the recognition of secured non-recourse debt liabilities assumed as part of the NPS Pharma acquisition.

#### **Other current liabilities**

Other current liabilities decreased by \$117.0 million to \$145.5 million at June 30, 2015 (December 31, 2014: \$262.5 million) principally due to the reduction in the fair value of contingent consideration payable associated with the SHP625 IPR&D intangible asset.

#### **Non-current deferred tax liabilities**

Non-current deferred tax liabilities increased by \$1,597.8 million to \$2,808.4 million at June 30 2015 (December 31, 2014: \$1,210.6 million) primarily due to deferred tax liabilities arising on intangible assets partially offset by deferred tax assets arising on tax attributes both acquired with NPS Pharma and Meritage.

#### **Other non-current liabilities**

Other non-current liabilities decreased by \$18.0 million to \$718.7 million at June 30, 2015 (December 31, 2014: \$736.7 million) principally due the reduction in the fair value of contingent consideration payable associated with the SHP608 IPR&D intangible asset, offset by the recognition of contingent consideration payable in respect of the Meritage acquisition.

## Liquidity and capital resources

### General

The Group's funding requirements depend on a number of factors, including the timing and extent of its development programs; corporate, business and product acquisitions; the level of resources required for the expansion of certain manufacturing and marketing capabilities as the product base expands; increases in accounts receivable and inventory which may arise with any increase in product sales; competitive and technological developments; the timing and cost of obtaining required regulatory approvals for new products; the timing and quantum of milestone payments on business combinations, in-licenses and collaborative projects; the timing and quantum of tax and dividend payments; the timing and quantum of purchases by the Employee Benefit Trust of Shire shares in the market to satisfy awards granted under Shire's employee share plans; and the amount of cash generated from sales of Shire's products and royalty receipts.

An important part of Shire's business strategy is to protect its products and technologies through the use of patents, proprietary technologies and trademarks, to the extent available. The Group intends to defend its intellectual property and as a result may need cash for funding the cost of litigation.

The Group finances its activities through cash generated from operating activities; credit facilities; private and public offerings of equity and debt securities; and the proceeds of asset or investment disposals.

Shire's balance sheet includes \$64.0 million of cash and cash equivalents at June 30, 2015.

Shire has a revolving credit facility of \$2,100 million which matures in 2019, \$920 million of which was utilized as June 30, 2015 to partially finance the purchase price paid in respect of Shire's acquisition of NPS Pharma (including certain related costs).

In connection with its acquisition of NPS Pharma, on January 11, 2015 the Group also entered into a \$850 million term loan facility agreement, which matures on January 10, 2016, with, among others, Citi Global Markets Limited (acting as mandated lead arranger and bookrunner) (the "2015 Facility Agreement"). At June 30, 2015 the 2015 Facility Agreement was fully utilized and recorded within short term borrowings. The Group also assumed non-recourse secured debt obligations as part of the NPS Pharma acquisition with a carrying value of \$83.8 million as at June 30, 2015. See note 13 of this Half Yearly Report for details.

In connection with its acquisition of ViroPharma, on November 11, 2013 the Group also entered into a \$2,600 million term loan facilities agreement with, among others, Morgan Stanley Bank International Limited (acting as lead arranger and agent) (the "2013 Facilities Agreement"). Amounts drawn under the 2013 Facilities Agreement were subsequently reduced to \$400 million. At June 30, 2015 the 2013 Facilities Agreement comprises a \$400 million term loan facility which matures on November 11, 2015, and was fully utilized and recorded within short term borrowings.

Shire has access to certain short term uncommitted lines of credit which it utilizes from time to time to provide short term flexibility in cash management. At June 30, 2015, \$50 million was drawn under such facilities.

### Financing

Shire anticipates that its operating cash flow together with available cash, cash equivalents and the RCF will be sufficient to meet its anticipated future operating expenses, capital expenditures, tax and interest payments, lease obligations, repayment of the term loans and milestone payments as they become due over the next twelve months.

If the Group decides to acquire other businesses, it expects to fund these acquisitions from cash resources, the RCF, and through new borrowings or the issuance of new equity if necessary.

## Sources and uses of cash

The following table provides an analysis of the Group's gross and net (debt)/cash position (excluding restricted cash), as at June 30, 2015 and December 31, 2014:

	June 30, 2015 \$'M	December 31, 2014 \$'M
Cash and cash equivalents <sup>(1)</sup>	64.0	2,982.4
Long term borrowings	(73.9)	-
Short term borrowings	(2,229.9)	(850.0)
Other debt	(13.6)	(13.7)
Total debt	(2,317.4)	(863.7)
Net (debt)/cash <sup>(2)</sup>	(2,253.4)	2,118.7

(1) Substantially all of the Group's cash and cash equivalents are held by foreign subsidiaries (i.e. those subsidiaries incorporated outside of Jersey, Channel Islands, the jurisdiction of incorporation of Shire plc, Shire's holding company). The amount of cash and cash equivalents held by foreign subsidiaries has not had, and is not expected to have, a material impact on the Group's liquidity and capital resources.

(2) Net(debt)/ cash is a Non-GAAP measure. The Group believes that Net (debt)/cash is a useful measure as it indicates the level of borrowings after taking account the cash and cash equivalents that could be utilized to pay down the outstanding borrowings.

## Cash flow activity

Net cash provided by operating activities in the six months to June 30, 2015 decreased by \$66.2 million or 6% to \$1,013.9 million (2014: \$1,080.1 million), as higher cash receipts from gross product sales was held back by the cash outflows related to the acquisition and integration of NPS Pharma. Net cash provided by operating activities in the six months to June 30, 2014 also benefited from a \$248 million repayment received from the Canadian revenue authorities.

Net cash used in investing activities was \$5,234.1 million in the six months to June 30, 2015, principally relating to the cash paid for the acquisition of NPS Pharma of \$5,220 million (less cash acquired with NPS Pharma of \$42 million) and for the acquisition of Meritage of \$75 million.

Net cash used in investing activities was \$3,938.1 million in the six months to June 30, 2014, principally relating to the cash paid for the acquisition of ViroPharma of \$3,997 million (net of cash acquired with ViroPharma of \$233 million) and for the acquisition of Lumena of \$300 million (net of cash acquired with Lumena of \$46 million).

Net cash provided by financing activities was \$1,302.5 million for the six months to June 30, 2015, principally due to the drawings, net of subsequent repayments, made under Shire's RCF, 2015 Facility Agreement and short term credit lines to partially fund the NPS Pharma acquisition.

Net cash provided by financing activities was \$773.3 million for the six months to June 30, 2014, principally due to the drawings, net of subsequent repayments, made under the RCF and Facilities to partially fund the ViroPharma acquisition. In addition the Group paid cash of \$551.5 million to settle the convertible debt assumed with ViroPharma, received cash of \$346.7 million upon settlement of a purchased call option acquired with ViroPharma and made a dividend payment of \$99.6 million.

## Obligations and commitments

Other than the borrowings incurred to finance, or assumed following, the acquisition of NPS Pharma, as outlined above, during the six months to June 30, 2015 there have been no material changes to the Group's contractual obligations previously disclosed in the Review of our Business in Shire's Annual Report and Accounts for the year ended December 31, 2013.

## Principal risks and uncertainties

The Group has adopted a risk management strategy designed to identify, assess and manage the significant risks that it faces. While the Group aims to identify and manage such risks, no risk management strategy can provide absolute assurance against loss.

The principal risks and uncertainties affecting the Group for the remaining six months of 2015 are those described under the headings below. It is not anticipated that the nature of the principal risks and uncertainties disclosed in the Annual Report and Accounts of Shire plc for the year ended December 31, 2014 will change in respect of the second half of 2015.

The Group's process for managing these risks is consistent with those processes as outlined in the Annual Report and Accounts of Shire plc for the year ended December 31, 2014. Some of these risks are specific to the Group and others are more generally applicable to the healthcare industry in which the Group operates. The Annual Report and Accounts are available on the Group's website, [www.shire.com](http://www.shire.com).

In summary, these risks and uncertainties were as follows:

Risk factors related to the Group's business:

- The Group's products may not be a commercial success.
- Product sales from ADDERALL XR and INTUNIV are subject to generic competition.
- The failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payers in a timely manner for the Group's products may impact future revenues, financial condition and results of operations.
- The Group 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 the Group's products or ingredients are only available from a single approved source for manufacture. Any disruption to the supply chain for any of the Group's products may result in the Group being unable to continue marketing or developing a product or may result in the Group being unable to do so on a commercially viable basis for some period of time.
- The manufacture of the Group's products is subject to extensive oversight by various regulatory agencies. Regulatory approvals or interventions associated with changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, an increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches.
- The Group 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 the Group's ability to sell or market products profitably. Fluctuations in buying or distribution patterns by such customers can adversely affect the Group's revenues, financial condition or results of operations.
- Investigations or enforcement action by regulatory authorities or law enforcement agencies relating to the Group'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.
- Adverse outcomes in legal matters 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 Group's revenues, financial condition or results of operations.
- The Group faces intense competition for highly qualified personnel from other companies and organizations. The Group is undergoing a corporate reorganization and was the subject of an unsuccessful acquisition proposal and the consequent uncertainty could adversely affect the Group's ability to attract and/or retain the highly skilled personnel needed for the Group to meet its strategic objectives.
- Failure to achieve the Group's strategic objectives with respect to the acquisition of NPS Pharma may adversely affect the Group's financial condition and results of operations.

General risk factors related to the Group and to the healthcare industry:

- The actions of governments, industry regulators and the economic environments in which the Group operates may adversely affect its ability to develop and profitably market its products.
- A slowdown of global economic growth, or economic instability of countries in which the Group does business, could have negative consequences for the Group's business and increase the risk of non-payment by the Group's customers.
- The Group is subject to evolving and complex tax laws, which may result in additional liabilities that may adversely affect the Group's financial condition or results of operations.
- The failure of a strategic partner to develop and commercialize products could result in delays in development, approval or loss of revenue.
- The failure to secure new products or compounds for development either through in-licensing, acquisition or internal research and development efforts, or the failure to realize expected benefits from acquisitions of businesses or products, may have an adverse impact on the Group's future results.
- The Group may fail to obtain, maintain, enforce or defend the intellectual property rights required to conduct its business.
- The introduction of new products by competitors may impact future revenues.
- If a marketed product fails to work effectively or causes adverse side effects, this could result in damage to the Group's reputation, the withdrawal of the product and legal action against the Group.

## Half Yearly Report

### Directors' responsibility statement

The Directors confirm that this condensed consolidated set of financial statements has been prepared in accordance with US GAAP and that the Half Yearly Report herein includes a fair review of the information required by DTR 4.2.7R and DTR 4.2.8R.

The Directors of Shire plc are listed in Shire's Annual Report and Accounts for the year ended December 31, 2014, with the exception of the following changes:

- David Stout stood down from the Board on April 28, 2015;
- Jeffrey Poulton was appointed Chief Financial Officer on April 30, 2015; and
- Olivier Bohuon was appointed as a non-executive director on July 1, 2015.

Details of all current Directors are available on Shire's website at [www.shire.com](http://www.shire.com).

On behalf of the Board:

Flemming Ornskov, M.D.  
Chief Executive Officer  
July 30, 2015

Jeffrey Poulton  
Chief Financial Officer  
July 30, 2015

## SHIRE PLC UNAUDITED CONSOLIDATED BALANCE SHEETS

	Notes	June 30, 2015 \$'M	December 31, 2014 \$'M
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents		64.0	2,982.4
Restricted cash		74.0	54.6
Accounts receivable, net	5	1,099.2	1,035.1
Inventories	6	632.8	544.8
Deferred tax asset		455.4	344.7
Prepaid expenses and other current assets	8	221.6	221.5
<b>Total current assets</b>		<b>2,547.0</b>	<b>5,183.1</b>
Non-current assets:			
Investments		50.0	43.7
Property, plant and equipment, net ("PP&E")		816.7	837.5
Goodwill	9	4,173.2	2,474.9
Other intangible assets, net	10	9,310.4	4,934.4
Deferred tax asset		107.9	112.1
Other non-current assets		25.3	46.4
<b>Total assets</b>		<b>17,030.5</b>	<b>13,632.1</b>
<b>LIABILITIES AND EQUITY</b>			
Current liabilities:			
Accounts payable and accrued expenses	11	1,939.7	1,909.4
Short-term borrowings	13	2,229.9	850.0
Other current liabilities	12	145.5	262.5
<b>Total current liabilities</b>		<b>4,315.1</b>	<b>3,021.9</b>
Non-current liabilities:			
Long-term borrowings	13	73.9	-
Deferred tax liability		2,808.4	1,210.6
Other non-current liabilities	14	718.7	736.7
<b>Total liabilities</b>		<b>7,916.1</b>	<b>4,969.2</b>
Commitments and contingencies	15		



**SHIRE PLC**  
**UNAUDITED CONSOLIDATED BALANCE SHEETS (continued)**

	Notes	June 30, 2015 \$'M	December 31, 2014 \$'M
	_____	_____	_____
Equity:			
Common stock of 5p par value; 1,000 million shares authorized; and 600.5 million shares issued and outstanding (2014: 1,000 million shares authorized; and 599.1 million shares issued and outstanding)		58.9	58.7
Additional paid-in capital		4,409.3	4,338.0
Treasury stock: 9.8 million shares (2014: 10.6 million shares)		(323.5)	(345.9)
Accumulated other comprehensive loss	16	(111.5)	(31.5)
Retained earnings		5,081.2	4,643.6
<b>Total equity</b>		<b>9,114.4</b>	<b>8,662.9</b>
<b>Total liabilities and equity</b>		<b>17,030.5</b>	<b>13,632.1</b>

The accompanying notes are an integral part of these unaudited consolidated financial statements.

## SHIRE PLC UNAUDITED CONSOLIDATED STATEMENTS OF INCOME

	Notes	6 months to June 30, 2015 \$'M	6 months to June 30, 2014 \$'M
Revenues:			
Product sales		2,899.4	2,777.7
Royalties		141.9	61.5
Other revenues		4.7	9.7
<b>Total revenues</b>		<b>3,046.0</b>	<b>2,848.9</b>
Costs and expenses:			
Cost of product sales		455.8	506.5
Research and development <sup>(1)</sup>		969.6	597.4
Selling, general and administrative <sup>(1)</sup>		1,133.9	926.5
Gain on sale of product rights		(12.3)	(40.2)
Reorganization costs	3	28.5	95.2
Integration and acquisition costs	4	(136.7)	118.7
<b>Total operating expenses</b>		<b>2,438.8</b>	<b>2,204.1</b>
<b>Operating income from continuing operations</b>		<b>607.2</b>	<b>644.8</b>
Interest income		2.6	19.2
Interest expense		(20.9)	(18.9)
Other income, net		2.3	8.0
<b>Total other (expense)/income, net</b>		<b>(16.0)</b>	<b>8.3</b>
<b>Income from continuing operations before income taxes and equity in (losses)/earnings of equity method investees</b>		<b>591.2</b>	<b>653.1</b>
Income taxes	21	(13.3)	125.9
<b>Equity in (losses)/earnings of equity method investees, net of taxes</b>		<b>(0.9)</b>	<b>2.4</b>
<b>Income from continuing operations, net of taxes</b>		<b>577.0</b>	<b>781.4</b>
Loss from discontinued operations, net of taxes	7	(7.0)	(27.9)
<b>Net income</b>		<b>570.0</b>	<b>753.5</b>

(1) Research and development ("R&D") includes IPR&D intangible asset impairment charges of \$523.3 million for the six months to June 30, 2015 (2014: \$188.0 million). Selling, general and administrative ("SG&A") costs include amortization of intangible assets relating to intellectual property rights acquired of \$219.6 million for the six months to June 30, 2015 (2014: \$119.0 million).

**SHIRE PLC**  
**UNAUDITED CONSOLIDATED STATEMENTS OF INCOME (continued)**

	Notes	6 months to June 30, 2015	6 months to June 30, 2014
<b>Earnings per ordinary share - basic</b>			
Earnings from continuing operations		97.8c	133.6c
Loss from discontinued operations		(1.2c)	(4.8c)
Earnings per ordinary share - basic		96.6c	128.8c
<b>Earnings per ordinary share - diluted</b>			
Earnings from continuing operations		97.3c	132.3c
Loss from discontinued operations		(1.2c)	(4.7c)
Earnings per ordinary share - diluted		96.1c	127.6c
<b>Weighted average number of shares (millions):</b>			
Basic	19	589.8	585.3
Diluted	19	593.0	590.3

The accompanying notes are an integral part of these unaudited consolidated financial statements.

**SHIRE PLC**  
**UNAUDITED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

	<b>6 months to June 30, 2015 \$'M</b>	<b>6 months to June 30, 2014 \$'M</b>
Net income	570.0	753.5
Other comprehensive income:		
Foreign currency translation adjustments	(83.3)	10.2
Unrealized holding gain on available-for-sale securities (net of taxes of \$nil and \$2.1 million)	3.3	3.7
Comprehensive income	490.0	767.4

The components of accumulated other comprehensive income as at June 30, 2015 and December 31, 2014 are as follows:

	<b>June 30, 2015 \$'M</b>	<b>December 31, 2014 \$'M</b>
Foreign currency translation adjustments	(109.0)	(25.7)
Unrealized holding loss on available-for-sale securities, net of taxes	(2.5)	(5.8)
Accumulated other comprehensive loss	(111.5)	(31.5)

The accompanying notes are an integral part of these unaudited consolidated financial statements.

**SHIRE PLC**  
**UNAUDITED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**  
(In millions of US dollars except share data)

	Shire plc shareholders' equity						
	Common stock Number of shares M's	Common stock \$'M	Additional paid-in capital \$'M	Treasury stock \$'M	Accumulated other comprehensive loss \$'M	Retained earnings \$'M	Total equity \$'M
	As at January 1, 2015	599.1	58.7	4,338.0	(345.9)	(31.5)	4,643.6
Net income	-	-	-	-	-	570.0	570.0
Other comprehensive loss, net of tax	-	-	-	-	(80.0)	-	(80.0)
Options exercised	1.4	0.2	-	-	-	-	0.2
Share-based compensation	-	-	44.3	-	-	-	44.3
Tax benefit associated with exercise of stock options	-	-	27.0	-	-	-	27.0
Shares released by employee benefit trust to satisfy exercise of stock options	-	-	-	22.4	-	(22.2)	0.2
Dividends	-	-	-	-	-	(110.2)	(110.2)
As at June 30, 2015	600.5	58.9	4,409.3	(323.5)	(111.5)	5,081.2	9,114.4

The accompanying notes are an integral part of these unaudited consolidated financial statements.

### Dividends per share

During the six months to June 30, 2015 Shire plc declared and paid dividends of 19.09 US cents per ordinary share (equivalent to 57.27 US cents per ADS) totalling \$110.2 million.

## SHIRE PLC UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

	6 months to June 30, 2015 \$'M	6 months to June 30, 2014 \$'M
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income	570.0	753.5
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	291.8	204.8
Share-based compensation	44.3	55.7
Change in fair value of contingent consideration	(255.7)	21.4
Impairment of intangible assets	523.3	188.0
Write down of assets	-	13.0
Gain on sale of product rights	(12.3)	(40.2)
Unwind of inventory fair value step-ups	16.3	72.5
Other, net	11.1	14.1
Movement in deferred taxes	(79.4)	25.3
Equity in losses/(earnings) of equity method investees	0.9	(2.4)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(84.9)	(37.3)
Increase in sales deduction accruals	37.3	106.0
Increase in inventory	(37.4)	(11.7)
Decrease/(increase) in prepayments and other assets	28.4	(137.5)
Decrease in accounts and notes payable and other liabilities	(39.8)	(145.1)
Net cash provided by operating activities <sup>(A)</sup>	1,013.9	1,080.1
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Movements in restricted cash	(19.5)	(11.9)
Purchases of subsidiary undertakings and businesses, net of cash acquired	(5,249.2)	(4,018.3)
Purchases of non-current investments	(4.9)	(3.1)
Purchases of PP&E	(39.8)	(19.1)
Proceeds from short-term investments	67.0	56.3
Proceeds received on sale of product rights	8.8	52.8
Proceeds from disposal of non-current investments	4.4	8.0
Other, net	(0.9)	(2.8)
Net cash used in investing activities <sup>(B)</sup>	(5,234.1)	(3,938.1)

**SHIRE PLC**  
**UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)**

	<b>6 months to June 30, 2015 \$'M</b>	<b>6 months to June 30, 2014 \$'M</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from revolving line of credit, long term and short term borrowings	2,925.6	2,310.8
Repayment of revolving line of credit and short term borrowings	(1,530.9)	(1,251.6)
Repayment of debt acquired through business combinations	-	(551.5)
Proceeds from ViroPharma call options	-	346.7
Payment of dividend	(110.2)	(99.6)
Excess tax benefit associated with exercise of stock options	27.0	29.1
Contingent consideration payments	(4.5)	(10.3)
Other, net	(4.5)	(0.3)
<b>Net cash provided by financing activities<sup>(C)</sup></b>	<b>1,302.5</b>	<b>773.3</b>
<b>Effect of foreign exchange rate changes on cash and cash equivalents<sup>(D)</sup></b>	<b>(0.7)</b>	<b>(1.1)</b>
<b>Net decrease in cash and cash equivalents<sup>(A+B+C+D)</sup></b>	<b>(2,918.4)</b>	<b>(2,085.8)</b>
Cash and cash equivalents at beginning of period	2,982.4	2,239.4
Cash and cash equivalents at end of period	64.0	153.6

**Supplemental information associated with continuing operations:**

	<b>6 months to June 30, 2015 \$'M</b>	<b>6 months to June 30, 2014 \$'M</b>
Interest paid	(9.9)	(7.7)
Income taxes repaid	65.2	248.0
Income taxes paid	(65.2)	(165.1)

The accompanying notes are an integral part of these unaudited consolidated financial statements.

## SHIRE PLC NOTES TO THE UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

### 1. Summary of Significant Accounting Policies

#### (a) *Basis of preparation*

These interim financial statements of Shire plc and its subsidiaries (collectively “Shire” or the “Group”) and other financial information included in this Half Yearly Report, are unaudited. They have been prepared in accordance with generally accepted accounting principles in the United States of America (“US GAAP”) and US Securities and Exchange Commission (“SEC”) regulations for interim reporting.

The balance sheet as at December 31, 2014 was derived from audited financial statements but does not include all disclosures required by US GAAP.

These interim financial statements should be read in conjunction with the consolidated financial statements and accompanying notes included in Shire’s Annual Report and Accounts for the year to December 31, 2014.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with US GAAP have been condensed or omitted from these interim financial statements. However, these interim financial statements include all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary to fairly state the results of the interim period and the Group believes that the disclosures are adequate to make the information presented not misleading. Interim results are not necessarily indicative of results to be expected for the full year.

#### (b) *Use of estimates in interim financial statements*

The preparation of interim financial statements, in conformity with US GAAP and SEC regulations, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of revenues and expenses during the reporting period. Estimates and assumptions are primarily made in relation to the valuation of intangible assets, sales deductions, income taxes (including provisions for uncertain tax positions and the realization of deferred tax assets), provisions for litigation and legal proceedings, contingent consideration receivable from product divestments and contingent consideration payable in respect of business combinations and asset purchases. If actual results differ from the Group’s estimates, or to the extent these estimates are adjusted in future periods, the Group’s results of operations could either benefit from, or be adversely affected by, any such change in estimate.

#### (c) *New accounting pronouncements*

##### *Adopted during the period*

##### Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity

In April 2014 the Financial Accounting Standards Board (“FASB”) issued guidance on the reporting of discontinued operations and disclosures of disposals of components of an entity. The amendments in this update revise the definition of discontinued operations by limiting discontinued operations reporting to disposals of components of an entity that represent strategic shifts that have (or will have) a major effect on an entity’s operations and financial results. The guidance requires expanded disclosures for discontinued operations which provide users of financial statements with more information about the assets, liabilities, revenues, and expenses of discontinued operations. The guidance also requires an entity to disclose the pre-tax profit or loss of an individually significant component of an entity that does not qualify for discontinued operations reporting.

Shire adopted this guidance in the period, which will be effective for discontinued operations occurring after January 1, 2015. The adoption of this guidance did not impact the Group’s consolidated financial position, results of operations or cash flows.

##### *To be adopted in future periods*

##### Revenue from Contracts with Customers

In May 2014 the FASB and the International Accounting Standards Board (together the “Accounting Standards Boards”) issued a new accounting standard that is intended to clarify and converge the financial reporting requirements for revenue from contracts with customers. The core principle of the standard is that an “entity



recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services". To achieve that core principle the Accounting Standards Boards developed a five-step model (as presented below) and related application guidance, which will replace most existing revenue recognition guidance in US GAAP.

*Five-step model:*

Step 1: Identify the contract(s) with a customer.

Step 2: Identify the performance obligations in the contract.

Step 3: Determine the transaction price.

Step 4: Allocate the transaction price to the performance obligations in the contract.

Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

The Accounting Standards Boards also issued new qualitative and quantitative disclosure requirements as part of the new accounting standard which aims to enable financial statement users to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

In July 2015 the FASB decided to defer the effective date of the guidance by one year. Based on this deferral, public entities would need to apply the new guidance for annual reporting periods beginning after December 15, 2017, and interim periods therein. The Group is currently evaluating the impact of adopting this guidance.

### Amendments to the Consolidation Analysis

In February 2015 the FASB issued guidance to respond to stakeholders' concerns about the current accounting for consolidation of certain legal entities. Financial statement users asserted that in certain situations in which consolidation is ultimately required, deconsolidated financial statements are necessary to better analyze the reporting entity's economic and operational results. Previously, the FASB issued an indefinite deferral for certain entities to partially address those concerns. However, the amendments in this guidance rescind that deferral and address those concerns by making changes to the consolidation guidance.

Under the amendments, all reporting entities are within the scope of Subtopic 810-10, Consolidation, including limited partnerships and similar legal entities, unless a scope exception applies. The presumption that a general partner controls a limited partnership has been eliminated. In addition, fees paid to decision makers that meet certain conditions no longer cause decision makers to consolidate a VIE in certain instances. The amendments place more emphasis in the consolidation evaluation on variable interests other than fee arrangements such as principal investment risk (for example, debt or equity interests), guarantees of the value of the assets or liabilities of the VIE, written put options on the assets of the VIE, or similar obligations, including some liquidity commitments or agreements (explicit or implicit). Additionally, the amendments reduce the extent to which related party arrangements cause an entity to be considered a primary beneficiary.

The amendments are effective for public business entities for fiscal years, and for interim periods therein, beginning after December 15, 2015. Early adoption is permitted, including adoption in an interim period. The Group does not expect the adoption of this guidance to have a material effect on its consolidated financial position, results of operations and cash flows.

### Simplifying the Presentation of Debt Issuance Costs

In April 2015 the FASB issued guidance to simplify the presentation of debt issuance costs. The guidance requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this update. The amendments in this update are effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods therein.

Early adoption of the amendments in this update is permitted for financial statements that have not been previously issued. An entity should apply the new guidance on a retrospective basis, wherein the balance sheet of each individual period presented should be adjusted to reflect the period-specific effects of applying the new guidance. Upon transition, an entity is required to comply with the applicable disclosures for a change in an accounting principle. The Group does not expect the adoption of this guidance to have a material effect on its consolidated financial position, results of operations and cash flows.

### Customer's Accounting for Fees Paid in a Cloud Computing Arrangement

In April 2015 the FASB issued guidance to simplify the customer's accounting for fees paid in a cloud computing arrangement. The amendments provide guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses.

If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The amendments will be effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted for all entities. An entity can elect to adopt the guidance either a) prospectively to all arrangements entered into or materially modified after the effective date or b) retrospectively. The Group is currently evaluating the impact of adopting this guidance.

### **(d) Going concern**

Shire anticipates that its operating cash flow together with available cash, cash equivalents and the RCF will be sufficient to meet its anticipated future operating expenses, capital expenditures, tax and interest payments, lease obligations, repayment of the term loans and milestone payments as they become due over the next twelve months.

The Directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future. Accordingly, the Directors continue to adopt the going concern basis of accounting in preparing the half-yearly report.

## **2. Business combinations**

### *Acquisition of NPS Pharma*

On February 21, 2015 Shire completed its acquisition of 100% of the outstanding share capital of NPS Pharma. The acquisition-date fair value of cash consideration paid on closing was \$5,220 million.

The acquisition of NPS Pharma added GATTEX/REVESTIVE, approved in the US and EU for the treatment of adults with short bowel syndrome (“SBS”), a rare and potentially fatal gastrointestinal disorder and NATPARA/NATPAR approved in the US for the treatment of hypoparathyroidism (“HPT”), a rare endocrine disease, to Shire’s portfolio of currently marketed products.

The acquisition of NPS Pharma has been accounted for as a business combination using the acquisition method. The assets acquired and the liabilities assumed from NPS Pharma have been recorded at their preliminary fair values at the date of acquisition, being February 21, 2015. The Group’s consolidated financial statements include the results of NPS Pharma from February 21, 2015.

The amount of NPS Pharma’s post-acquisition revenues and pre-tax losses included in the Group’s consolidated statement of income for the six months to June 30, 2015 were \$107.1 million and \$159.9 million respectively. The pre-tax loss includes charges on the unwind of inventory fair value adjustments of \$15.1 million, intangible asset amortization of \$101.5 million and integration costs of \$60.7 million.

During the second quarter of 2015, within the measurement period, the Group obtained both additional and improved information about the acquisition-date fair value of NPS Pharma inventories. This information included: an assessment and alignment of NPS Pharma’s policy for classifying inventories as raw material, work-in-progress or finished goods with that of Shire; insight into the amount and carrying value of short-lived inventories; and insight into inventories which were available for commercial sale that were previously expensed by NPS Pharma as they were manufactured prior to the necessary regulatory approval. The Group’s preliminary allocation of the purchase price to the assets acquired and liabilities assumed, including the measurement period adjustment with respect to inventories and certain other immaterial measurement period adjustments, is outlined below:

	Preliminary Fair value \$'M
<b>ASSETS</b>	
Current assets:	
Cash and cash equivalents	41.6
Short-term investments	67.0
Accounts receivable	33.4
Inventories	89.4
Deferred tax assets	156.3
Other current assets	11.1
<b>Total current assets</b>	<b>398.8</b>
Non-current assets:	
PP&E	4.8
Goodwill	1,679.4
Other intangible assets	
- currently marketed products	4,640.0
- royalty rights (categorized as "Other amortized intangible assets" )	353.0
<b>Total assets</b>	<b>7,076.0</b>
<b>LIABILITIES</b>	
Current liabilities:	
Accounts payable and other current liabilities	72.5
Short-term debt	27.4
Non-current liabilities:	
Long-term debt, less current portion	78.9
Deferred tax liabilities	1,673.1
Other non-current liabilities	4.5
<b>Total liabilities</b>	<b>1,856.4</b>
<b>Fair value of identifiable assets acquired and liabilities assumed</b>	<b>5,219.6</b>
<b>Consideration</b>	
Cash consideration paid	<b>5,219.6</b>

The purchase price allocation is preliminary pending final determination of the fair values of certain assets and liabilities. In particular the fair values of intangible assets and current and deferred tax assets and liabilities are preliminary pending receipt of the final valuations for those items. The final determination of these fair values will be completed as soon as possible but no later than one year from the acquisition date.

*(a) Other intangible assets – currently marketed products*

Other intangible assets totaling \$4,640.0 million relate to intellectual property rights acquired for NPS Pharma's currently marketed products, primarily attributed to NATPARA/NATPAR, and GATTEX/REVESTIVE. The fair value of the currently marketed products is preliminary and has been estimated using an income approach, based on the present value of incremental after tax cash flows attributable to each separately identifiable intangible asset.

The estimated useful lives of the NATPARA/NATPAR and GATTEX/REVESTIVE intangible assets are 24 years, with amortization being recorded on a straight-line basis.

## (b) Other intangible assets – Royalty rights

Other intangibles totaling \$353.0 million relate to the royalty rights arising from the collaboration agreements with Amgen, Janssen and Kyowa Hakko Kirin. Amgen markets cinacalcet HCl as Sensipar in the US and as Mimpara in the EU; Janssen Pharmaceuticals markets tapentadol as Nucynta in the US; and Kyowa Hakko Kirin markets cinacalcet HCl as Regpara in Japan, Hong Kong, Malaysia, Macau, Singapore, and Taiwan. NPS Pharma is entitled to royalties from the relevant net sales of these products.

The fair value of these royalty rights is preliminary and has been estimated using an income approach, based on the present value of incremental after tax cash flows attributable to each royalty right.

The estimated useful lives of these royalty rights range from 4 to 5 years (weighted average 4 years), with amortization being recorded on a straight-line basis.

## (c) Goodwill

Goodwill arising of \$1,679.4 million, which is not deductible for tax purposes, includes the expected synergies that will result from combining the operations of NPS Pharma with the operations of Shire; particularly those synergies expected to be realized due to Shire's structure; intangible assets that do not qualify for separate recognition at the time of the acquisition; and the value of the assembled workforce.

In the six months to June 30, 2015 the Group expensed costs of \$117.7 million, relating to the acquisition and post-acquisition integration of NPS Pharma, which have been recorded within Integration and acquisition costs in the Group's consolidated statement of income.

## Supplemental disclosure of pro forma information

The following unaudited pro forma financial information presents the combined results of the operations of Shire and NPS Pharma as if the acquisition of NPS Pharma had occurred as at January 1, 2014. The unaudited pro forma financial information is not necessarily indicative of what the consolidated results of operations actually would have been had the acquisition been completed at the date indicated. In addition, the unaudited pro forma financial information does not purport to project the future results of operations of the combined Group.

	6 months to June 30, 2015 \$'M	6 months to June 30, 2014 \$'M
Revenues	3,075.9	2,949.0
Net income from continuing operations	526.6	565.7
Per share amounts:		
Net income from continuing operations per share - basic	95.9c	96.6c
Net income from continuing operations per share - diluted	95.4c	95.8c

The unaudited pro forma financial information above reflects the following pro forma adjustments:

- (i) an adjustment to decrease net income by \$107.2 million for the period to June 30, 2014 to reflect acquisition costs incurred by Shire and NPS Pharma, and increase net income by \$107.2 million for the period to June 30, 2015 to eliminate acquisition costs incurred;
- (ii) an adjustment to decrease net income by \$9.2 million for the period to June 30, 2014 to reflect charges on the unwind of inventory fair value adjustments as acquisition date inventory is sold, and a corresponding increase in net income for the period to June 30, 2015;
- (iii) an adjustment of \$11.1 million in the period to June 30, 2014 to reflect additional interest expense associated with the drawdown of debt to partially finance the acquisition of NPS Pharma and the amortization of related deferred debt issuance costs;

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- (iv) an adjustment to increase amortization expense by approximately \$21.1 million in the period to June 30, 2015 and \$83.6 million in the period to June 30, 2014 related to amortization of the fair value of identifiable intangible assets acquired and the elimination of NPS Pharma's historical intangible asset amortization expense; and

The adjustments above are stated net of their tax effects, where applicable.

### *Acquisition of Meritage Pharma Inc. ("Meritage")*

Prior to the acquisition of ViroPharma by Shire (see below), ViroPharma had entered into an exclusive development and option agreement with Meritage, a privately owned US company focusing on developing oral budesonide suspension ("OBS") as a treatment for eosinophilic esophagitis. Under the terms of this agreement Meritage controlled and conducted all related research up to achievement of pre-defined development success criteria at which point ViroPharma had the option to acquire Meritage.

On February 18, 2015, following the exercise of the purchase option, Shire acquired all the outstanding equity of Meritage. The acquisition date fair value of the consideration totaled \$166.9 million, comprising cash consideration paid on closing of \$74.8 million and the fair value of contingent consideration payable of \$92.1 million. The maximum amount of contingent cash consideration which may be payable by Shire in future periods is \$175.0 million dependent upon achievement of certain clinical development and regulatory milestones.

With the Meritage acquisition, Shire has acquired the global rights to Meritage's Phase 3-ready compound, OBS, for the treatment of adolescents and adults with eosinophilic esophagitis.

The acquisition of Meritage has been accounted for as a business combination using the acquisition method. The assets and liabilities assumed from Meritage have been recorded at their preliminary fair values at the date of acquisition, being February 18, 2015. The Group's consolidated financial statements and results of operations include the results of Meritage from February 18, 2015.

The purchase price allocation is preliminary pending the determination of the fair values of certain assets and liabilities. The purchase price has been allocated on a preliminary basis to the OBS IPR&D intangible asset (\$175 million), net current assets assumed (\$5.5 million), net non-current liabilities assumed (including deferred tax liabilities) (\$54.7 million) and goodwill (\$41.1 million). Goodwill arising of \$41.1 million is not deductible for tax purposes.

Unaudited pro forma financial information to present the combined results of operations of Shire and Meritage is not provided as the impact of this acquisition is not material to the Group's results of operations for any period presented.

### *Acquisition of ViroPharma Incorporated ("ViroPharma")*

On January 24, 2014 Shire completed its acquisition of 100% of the outstanding share capital of ViroPharma. The acquisition-date fair value of cash consideration paid on closing was \$3,997 million.

The acquisition of ViroPharma added CINRYZE to Shire's portfolio of currently marketed products. CINRYZE is a leading brand for the prophylactic treatment of Hereditary Angioedema ("HAE") in adolescents and adults.

The acquisition of ViroPharma has been accounted for as a business combination using the acquisition method. The assets acquired and the liabilities assumed from ViroPharma have been recorded at their fair values at the date of acquisition, being January 24, 2014. The Group's consolidated financial statements include the results of ViroPharma from January 24, 2014.

The purchase price allocation was finalized in the fourth quarter of 2014. The Group's allocation of the purchase price to the fair value of assets acquired and liabilities assumed is outlined below:

	Acquisition date fair value \$'M
Identifiable assets acquired and liabilities assumed	
<b>ASSETS</b>	
Current assets:	
Cash and cash equivalents	232.6
Short-term investments	57.8
Accounts receivable	52.2
Inventories	203.6
Deferred tax assets	100.7
Purchased call option	346.7
Other current assets	50.9
Total current assets	1,044.5
Non-current assets:	
PP&E	24.7
Goodwill	1,655.5
Other intangible assets	
- Currently marketed products	2,320.0
- In-Process Research and Development ("IPR&D")	315.0
Other non-current assets	10.4
Total assets	5,370.1
<b>LIABILITIES</b>	
Current liabilities:	
Accounts payable and other current liabilities	122.7
Convertible bond	551.4
Non-current liabilities:	
Deferred tax liabilities	603.5
Other non-current liabilities	95.5
Total liabilities	1,373.1
Fair value of identifiable assets acquired and liabilities assumed	3,997.0
<b>Consideration</b>	
Cash consideration paid	3,997.0

*(a) Other intangible assets – currently marketed products*

Other intangible assets totaled \$2,320.0 million at the date of acquisition, relating to intellectual property rights acquired for ViroPharma's then currently marketed products, primarily attributed to CINRYZE, for the routine prophylaxis against HAE attacks in adolescent and adult patients. Shire also obtained intellectual property rights to three other commercialized products, PLENADREN, an orphan drug for the treatment of adrenal insufficiency in adults, BUCCOLAM, an oromucosal solution for the treatment of prolonged, acute, and convulsive seizures in infants, toddlers, children and adolescents and VANCOCIN, an oral capsule formulation for the treatment of C. difficile-associated diarrhea ("CDAD"), which was divested by Shire in the third quarter of 2014. The fair value of currently

marketed products has been estimated using an income approach, based on the present value of incremental after tax cash flows attributable to each separately identifiable intangible asset.

The estimated useful lives of the CINRYZE, PLENADREN and BUCCOLAM intangible assets range from 10 to 23 years (weighted average 22 years), with amortization being recorded on a straight-line basis.

### *(b) Other intangible assets – IPR&D*

The IPR&D asset of \$315.0 million relates to maribavir (now SHP620), an investigational antiviral product for cytomegalovirus. The fair value of this IPR&D asset was estimated based on an income approach, using the present value of incremental after tax cash flows expected to be generated by this development project after the deduction of contributory asset charges for other assets employed in this project. The estimated cash flows have been probability adjusted to take into account the stage of completion and the remaining risks and uncertainties surrounding the future development and commercialization.

The major risks and uncertainties associated with the timely completion of the acquired IPR&D project include the ability to confirm the efficacy of the technology based on the data from clinical trials, and obtaining the relevant regulatory approvals as well as other risks as described in the Annual Report and Accounts of Shire plc for the year ended December 31, 2014. The valuation of IPR&D has been based on information available at the time of the acquisition (and information obtained during the measurement period) and on expectations and assumptions that (i) have been deemed reasonable by the Group's management and (ii) are based on information, expectations and assumptions that would be available to a market participant. However, no assurance can be given that the assumptions and events associated with such assets will occur as projected. For these reasons, the actual cash flows may vary from forecast future cash flows.

The estimated probability adjusted after tax cash flows used in fair valuing other intangible assets have been discounted at rates ranging from 9.5% to 10.0%.

### *(c) Goodwill*

Goodwill arising of \$1,655.5 million, which is not deductible for tax purposes, includes the expected operational synergies that will result from combining the commercial operations of ViroPharma with those of Shire (valued at approximately \$400 million); other synergies expected to be realized due to Shire's structure; intangible assets that do not qualify for separate recognition at the time of the acquisition; and the value of the assembled workforce.

## **3. Reorganization costs**

### *One Shire business reorganization*

On May 2, 2013, the Group initiated the reorganization of its business to integrate the three divisions into a simplified One Shire organization in order to drive future growth and innovation.

In 2014 certain aspects of the One Shire program were temporarily put on hold due to AbbVie's offer for Shire, which was terminated in October 2014. Subsequent to the termination of AbbVie's offer, Shire announced on November 10, 2014 its plans to relocate over 500 positions to Lexington Massachusetts from its Chesterbrook, Pennsylvania, site and establish Lexington as the Group's US operational headquarters in continuation of the One Shire efficiency program. This relocation will streamline business globally through two principal locations, Massachusetts and Switzerland, with support from regional and country-based offices around the world.

In the six months to June 30, 2015 the Group incurred reorganization costs totaling \$28.5 million, respectively relating to employee involuntary termination benefits and other reorganization costs. Reorganization costs of \$274.0 million have been incurred since May 2013. The One Shire reorganization is expected to be substantially completed by the end of 2015. Currently, the Group estimates that further costs in respect of the One Shire reorganization of approximately \$102 million will be expensed as incurred during 2015.

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The liability for reorganization costs arising from the One Shire business reorganization at June 30, 2015 is as follows:

	Opening liability at January 1, 2015 \$'M	Amount charged to re- organization \$'M	Paid/Utilized \$'M	Closing liability at June 30, 2015 \$'M
Involuntary termination benefits	38.0	19.7	(26.4)	31.3
Other reorganization costs	-	8.8	(6.9)	1.9
	<u>38.0</u>	<u>28.5</u>	<u>(33.3)</u>	<u>33.2</u>

At June 30, 2015 the closing reorganization cost liability was recorded within accounts payable and accrued expenses.

#### 4. Integration and acquisition costs

For the six months to June 30, 2015 Shire recorded a net credit to integration and acquisition costs of \$136.7 million. The net credit principally comprises (i) costs related to the acquisition and integration of NPS Pharma (\$117.7 million in the six months to June 30, 2015), offset by (ii) a net credit relating to the change in the fair value of contingent consideration liabilities of \$255.7 million in the six months to June 30, 2015. The net credit relating to the change in fair value of contingent consideration liabilities principally relates to the acquisition of Lumena Pharmaceuticals, Inc. ("Lumena"), reflecting a lower probability of success for the SHP625 asset (for the treatment of cholestatic liver diseases) following the receipt of data from certain Phase 2 studies, and the acquisition of Lotus Tissue Repair, Inc. ("Lotus Tissue Repair"), reflecting a lower probability of success for the SHP608 asset (for the treatment of Dystrophic Epidermolysis Bullosa ("DEB")) as a result of certain preclinical toxicity findings (see note 10 for further details).

In the six months to June 30, 2014 Shire recorded integration and acquisition costs of \$118.7 million. In the six months to June 30, 2014 the charge comprised \$97.3 million relating to the acquisition and integration of ViroPharma and a net charge on the fair value of contingent consideration liabilities of \$21.4 million (principally in relation to SARcode, as outlined above, offset by credits in relation to the acquisition of FerroKin BioSciences, Inc, reflecting the decision to place the Phase 2 clinical trial for SHP602 on clinical hold).

#### 5. Accounts receivable, net

Accounts receivable at June 30, 2015 of \$1,099.2 million (December 31, 2014: \$1,035.1 million), are stated net of a provision for discounts and doubtful accounts of \$53.5 million (December 31, 2014: \$48.5 million).

Provision for discounts and doubtful accounts:

	2015 \$'M	2014 \$'M
As at January 1,	48.5	47.9
Provision charged to operations	186.6	163.1
Provision utilization	(181.6)	(165.7)
As at June 30,	<u>53.5</u>	<u>45.3</u>

At June 30, 2015 accounts receivable included \$69.8 million (December 31, 2014: \$59.0 million) related to royalty income.



## 6. Inventories

Inventories are stated at the lower of cost or market. Inventories comprise:

	June 30, 2015 \$'M	December 31, 2014 \$'M
Finished goods	136.8	136.0
Work-in-progress	383.1	305.3
Raw materials	112.9	103.5
	632.8	544.8

## 7. Results of discontinued operations

Following the divestment of the Group's DERMAGRAFT business in January 2014, the operating results associated with the DERMAGRAFT business have been classified as discontinued operations in the consolidated statements of income for all periods presented. In the six months to June 30, 2015 the Group recorded a loss, net of tax of \$7.0 million (2014: \$27.9 million) respectively, primarily relating to costs associated with the divestment.

## 8. Prepaid expenses and other current assets

	June 30, 2015 \$'M	December 31, 2014 \$'M
Prepaid expenses	57.9	36.9
Income tax receivable	107.7	121.5
Value added taxes receivable	17.4	13.8
Other current assets	38.6	49.3
	221.6	221.5

## 9. Goodwill

	June 30, 2015 \$'M	December 31, 2014 \$'M
Goodwill arising on businesses acquired	4,173.2	2,474.9

In the six months to June 30, 2015 the Group completed the acquisitions of NPS Pharma and Meritage, which resulted in aggregate goodwill with a preliminary value of \$1,720.5 million (see Note 2 for details).

	2015 \$'M	2014 \$'M
As at January 1,	2,474.9	624.6
Acquisitions	1,720.5	1,662.7
Foreign currency translation	(22.2)	(3.9)
As at June 30,	4,173.2	2,283.4

## 10. Other intangible assets, net

	June 30, 2015 \$'M	December 31, 2014 \$'M
Amortized intangible assets		
Intellectual property rights acquired for currently marketed products	9,416.1	4,816.9
Other intangible assets <sup>(1)</sup>	375.0	30.0
	<u>9,791.1</u>	<u>4,846.9</u>
Unamortized intangible assets		
Intellectual property rights acquired for IPR&D	1,182.2	1,550.0
	<u>10,973.3</u>	<u>6,396.9</u>
Less: Accumulated amortization	(1,662.9)	(1,462.5)
	<u>9,310.4</u>	<u>4,934.4</u>

(1) Other intangible assets primarily comprises of royalty right assets acquired with NPS Pharma.

The change in the net book value of other intangible assets for the six months to June 30, 2015 and 2014 is shown in the table below:

	<b>Other intangible assets</b>	
	2015 \$'M	2014 \$'M
As at January 1,	4,934.4	2,312.6
Acquisitions	5,167.8	3,321.4
Amortization charged	(219.6)	(119.0)
Impairment charges	(523.3)	(188.0)
Foreign currency translation	(48.9)	(1.5)
As at June 30,	<u>9,310.4</u>	<u>5,325.5</u>

In the six months to June 30, 2015 the Group acquired intangible assets totaling \$5,168 million, relating to the fair value of intangible assets for currently marketed products and royalty right assets acquired with NPS Pharma of \$4,993 million and IPR&D assets of \$175 million acquired with Meritage (see Note 2 for further details).

The Group reviews its intangible assets for impairment whenever events or circumstances suggest that their carrying value may not be recoverable. In the six months to June 30, 2015 the Group identified indicators of impairment in respect of its SHP625 (for the treatment of cholestatic liver disease), and SHP608 (for the treatment of DEB) IPR&D assets.

The indicators of impairment related to SHP625 in the second quarter of 2015 included the results of two Phase 2 studies, comprising a 13-week study of 20 paediatric patients with Alagille syndrome ("ALGS"), a 13 week, double blind, placebo-controlled trial in combination with ursodeoxycholic acid ("UDCA") for patients with Primary Biliary Cirrhosis ("PBC"), and preliminary results from a 72 week open label Phase 2 study in Progressive Familial Intrahepatic Cholestasis ("PFIC"). Although both the ALGS and PBC trials indicated a reduction in bile serum acids in the SHP625 treated group, neither of these trials met their primary or secondary endpoints. The interim analysis in the PFIC trial was based on the first 12 subjects who completed 13 weeks of treatment per protocol. There was no statistically significant reduction in mean serum bile acid levels from baseline. A change from baseline analysis was planned as there is no placebo treatment arm in this study. However, changes from baseline for pruritus did reach statistical significance.

Following these trial results, the Group reviewed the recoverability of its SHP625 IPR&D asset in the second quarter of 2015 and recorded an impairment charge of \$346.6 million (within R&D expenses in the consolidated statement of income) to record the SHP625 IPR&D asset to its revised fair value of \$120.4 million. This fair value was based on the revised discounted cash flow forecasts associated with SHP625, which included a reduced probability of achieving regulatory approval.

For SHP608, preclinical toxicity findings in the second quarter of 2015 have led to a significant reduction in the probability of achieving regulatory approval of this asset. As a result, the Group recorded an impairment charge of \$176.7 million within R&D expenses in the consolidated statement of income to fully write off the SHP608 IPR&D asset.

The fair values of the related contingent consideration liabilities arising from the Lumena and Lotus Tissue Repair acquisitions (through which Shire acquired SHP625 and SHP608 respectively) have also been reduced, resulting in a credit of \$280.0 million being recorded in Integration and acquisition costs.

In the six months to June 30, 2014 the Group identified indicators of impairment in respect of its SHP602 (iron chelating agent for the treatment of iron overload secondary to chronic transfusion) and SHP613 (for the treatment of improvement in patency of arteriovenous access in hemodialysis patients) IPR&D assets. The Group therefore reviewed the recoverability of its SHP602 and SHP613 IPR&D assets and recorded an impairment charge of \$166.0 million and \$22.0 million, respectively within R&D expenses in the consolidated statement of income to record the IPR&D assets to their revised fair value.

Management estimates that the annual amortization charge in respect of intangible assets held at June 30, 2015 will be approximately \$476 million for each of the five years to June 30, 2020. Estimated amortization expense can be affected by various factors including future acquisitions, disposals of product rights, regulatory approval and subsequent amortization of acquired IPR&D projects, foreign exchange movements and the technological advancement and regulatory approval of competitor products.

## 11. Accounts payable and accrued expenses

	June 30, 2015 \$'M	December 31, 2014 \$'M
Trade accounts payable and accrued purchases	286.8	247.7
Accrued rebates – Medicaid	606.5	563.9
Accrued rebates – Managed care	310.7	318.2
Sales return reserve	137.5	131.7
Accrued bonuses	121.0	150.7
Accrued employee compensation and benefits payable	150.3	109.1
R&D accruals	66.5	88.3
Other accrued expenses	260.4	299.8
	1,939.7	1,909.4

## 12. Other current liabilities

	June 30, 2015 \$'M	December 31, 2014 \$'M
Income taxes payable	60.6	16.2
Value added taxes	19.5	16.6
Contingent consideration payable	19.5	194.5
Other current liabilities	45.9	35.2
	145.5	262.5

## 13. Borrowings

	June 30, 2015 \$'M	December 31, 2014 \$'M
<b>Short term borrowings:</b>		
Borrowings under the 2015 Facility Agreement	850.0	-
Borrowings under the 2013 Facilities Agreement	400.0	850.0
Borrowings under the RCF	920.0	-
Borrowings under short term Credit lines	50.0	-
Secured non-recourse debts	9.9	-
	2,229.9	850.0
<b>Long term borrowings:</b>		
Secured non-recourse debts	73.9	-
	2,303.8	850.0

### Term Loan Agreements

#### *2015 Facility Agreement*

On January 11, 2015, Shire entered into an \$850 million Facility Agreement with, among others, CitiGroup Global Markets Limited (acting as mandated lead arranger and bookrunner) (the "2015 Facility Agreement"). At June 30, 2015 the 2015 Facility Agreement, which matures on January 10, 2016, was fully utilized. The maturity date may be extended twice, at Shire's option, by six months on each occasion.

The 2015 Facility Agreement has been used to partially finance the purchase price payable in respect of Shire's acquisition of NPS Pharma (including certain related costs). See the Shire's Annual Report and Accounts for details of the 2015 Facility Agreement.

#### *2013 Facilities Agreement*

On November 11, 2013, Shire entered into a \$2,600 million facilities agreement with, among others, Morgan Stanley Bank International Limited (acting as mandated lead arranger and bookrunner) (the "2013 Facilities Agreement"). The 2013 Facilities Agreement comprised two credit facilities: (i) a \$1,750 million term loan facility and (ii) an \$850 million term loan facility.

On December 13, 2013 and at various points thereafter, the Group cancelled parts of the \$2,600 million term loan facility. At June 30, 2015 the 2013 Facilities Agreement was comprised of a \$400 million term loan facility which matures on November 11, 2015 and was fully utilized.

The \$400 million remaining borrowing from the 2013 Facilities Agreement was used to partially finance the purchase price payable in respect of Shire's acquisition of ViroPharma (including certain related costs) during the year ended December 31, 2014. See Shire's 2014 Annual Report and Accounts for details of the 2013 Facilities Agreement.

### Revolving Credit Facility ("RCF")

On December 12, 2014, Shire entered into a \$2,100 million RCF with a number of financial institutions. See Shire's 2014 Annual Report and Accounts for details. At June 30, 2015 the Group has utilized \$920 million of the RCF to partially finance the purchase price payable in respect of Shire's acquisition of NPS Pharma (including certain related costs).

The RCF, which terminates on December 12, 2019, may be applied towards financing the general corporate purposes of Shire. The RCF incorporates a \$250 million US dollar and euro swingline facility operating as a sub-limit thereof.

### Secured Non-recourse Debts

Prior to the acquisition by Shire, NPS Pharma had:

- partially monetized rights to receive future royalty payments from Amgen's sales of SENSIPAR and MIMPARA through the issuance of \$145 million of non-recourse debt that is both serviced and secured by SENSIPAR and MIMPARA royalty revenue;

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- sold to DRI Capital Inc. (“DRI”) certain rights to receive up to \$96 million of future royalty payments arising from Kyowa Hakko Kirin’s sales of REGPARA and granted DRI a security interest in the license agreement with Kyowa Hakko Kirin, certain patents and other intellectual property related to REGPARA which DRI would be entitled to enforce in the event of default by NPS Pharma; and
- partially monetized PTH-184 (now marketed as NATPARA) through an agreement with an affiliate of DRI pursuant to which NPS Pharma, its licensees and its predecessors in interest, are obligated to pay up to \$125 million royalties on sales of PTH-184. Additionally, NPS Pharma granted DRI a security interest in certain patents and other intellectual property related to PTH 1-84 which DRI would be entitled to enforce in the event of default by NPS Pharma.

Following the acquisition of NPS Pharma the Group has assumed these secured non-recourse debt obligations.

In May 2015 the Group notified Amgen that it intended to repay in full the remaining non-recourse debt. The repayment was effected on May 15, 2015 by Amgen withholding certain royalties that were due to the Group from SENSIPAR and MIMPARA sales in the first quarter of 2015.

As at June 30, 2015 \$9.9 million has been included within Short-term borrowings, and \$73.9 million has been included within Long-term borrowings in respect of the remaining obligations to DRI.

### Short term uncommitted lines of credit (“Credit lines”)

Shire has access to various Credit lines from a number of banks which provide flexibility to short term cash management procedures. These Credit lines can be withdrawn by the banks at any time. The Credit lines are not relied upon for core liquidity. As at June 30, 2015 \$50 million was borrowed under these Credit lines.

## 14. Other non-current liabilities

	June 30, 2015 \$'M	December 31, 2014 \$'M
Income taxes payable	178.9	199.2
Contingent consideration payable	445.2	435.4
Other non-current liabilities	94.6	102.1
	718.7	736.7

## 15. Commitments and contingencies

### (a) Leases

Future minimum lease payments under operating leases at June 30, 2015 are presented below:

	Operating leases \$'M
2015	25.0
2016	42.1
2017	32.6
2018	25.0
2019	20.8
2020	20.0
Thereafter	125.9
	291.4

The Group leases land, facilities, motor vehicles and certain equipment under operating leases expiring through 2032. Lease and rental expense amounted to \$24.3 million and \$20.8 million for the six months to June 30, 2015 and 2014 respectively, which is predominately included in SG&A expenses in the Group's consolidated income statement.

### **(b) Letters of credit and guarantees**

At June 30, 2015 the Group had irrevocable standby letters of credit and guarantees with various banks and insurance companies totaling \$48.0 million (being the contractual amounts), providing security for the Group's performance of various obligations. These obligations are primarily in respect of the recoverability of insurance claims, lease obligations and supply commitments.

### **(c) Collaborative and other licensing arrangements**

Details of significant updates in collaborative and other licensing arrangements are included below:

#### *Out-licensing arrangements*

Shire has entered into various collaborative and out-licensing arrangements under which the Group has out-licensed certain product or intellectual property rights for consideration such as up-front payments, development milestones, sales milestones and/or royalty payments. In some of these arrangements Shire and the licensee are both actively involved in the development and commercialization of the licensed product and have exposure to risks and rewards dependent on its commercial success. Under the terms of these collaborative and out-licensing arrangements, the Group may receive development milestone payments up to an aggregate amount of \$39 million and sales milestones up to an aggregate amount of \$46 million. The receipt of these substantive milestones is uncertain and contingent on the achievement of certain development milestones or the achievement of a specified level of annual net sales by the licensee. In the six months to June 30, 2015 Shire received cash in respect of up-front and milestone payments totaling \$12.6 million (2014: \$1.0 million). In the six months to June 30, 2015 Shire recognized milestone income of \$1.0 million (2014: \$2.0 million) in other revenues and \$23.4 million (2014: \$26.4 million) in product sales for shipment of product to the relevant licensee.

### **(d) Commitments**

#### **(i) Clinical testing**

At June 30, 2015 the Group had committed to pay approximately \$430 million (December 31, 2014: \$382 million) to contract vendors for administering and executing clinical trials. The timing of these payments is dependent upon actual services performed by the organizations as determined by patient enrollment levels and related activities.

#### **(ii) Contract manufacturing**

At June 30, 2015 the Group had committed to pay approximately \$310 million (December 31, 2014: \$384 million) in respect of contract manufacturing. The Group expects to pay \$107 million of these commitments in 2015.

#### **(iii) Other purchasing commitments**

At June 30, 2015 the Group had committed to pay approximately \$275 million (December 31, 2014: \$265 million) for future purchases of goods and services, predominantly relating to active pharmaceutical ingredients sourcing. The Group expects to pay \$266 million of these commitments in 2015.

#### **(iv) Investment commitments**

At June 30, 2015 the Group had outstanding commitments to subscribe for interests in companies and partnerships for amounts totaling \$58 million (December 31, 2014: \$67 million) which may all be payable in 2015, depending on the timing of capital calls. The investment commitments include additional funding to certain VIEs of which Shire is not the primary beneficiary.

#### **(v) Capital commitments**

At June 30, 2015 the Group had committed to spend \$9 million (December 31, 2014: \$3 million) on capital projects.

## (e) *Legal and other proceedings*

The Group expenses legal costs as they are incurred.

The Group recognizes loss contingency provisions for probable losses when management is able to reasonably estimate the loss. When the estimated loss lies within a range, the Group records a loss contingency provision based on its best estimate of the probable loss. If no particular amount within that range is a better estimate than any other amount, the minimum amount is recorded. Estimates of losses may be developed substantially before the ultimate loss is known, and are therefore refined each accounting period as additional information becomes known. In instances where the Group is unable to develop a reasonable estimate of loss, no loss contingency provision is recorded at that time. As information becomes known a loss contingency provision is recorded when a reasonable estimate can be made. The estimates are reviewed quarterly and the estimates are changed when expectations are revised. An outcome that deviates from the Group's estimate may result in an additional expense or release in a future accounting period. At June 30, 2015, provisions for litigation losses, insurance claims and other disputes totaled \$8.5 million (December 31, 2014: \$16.9 million).

The Group's principal pending legal and other proceedings are disclosed below. The outcomes of these proceedings are not always predictable and can be affected by various factors. For those legal and other proceedings for which it is considered at least reasonably possible that a loss has been incurred, the Group discloses the possible loss or range of possible loss in excess of the recorded loss contingency provision, if any, where such excess is both material and estimable.

### *VYVANSE*

In May and June 2011, Shire was notified that six separate Abbreviated New Drug Applications ("ANDAs") were submitted under the Hatch-Waxman Act seeking permission to market generic versions of all approved strengths of VYVANSE. The notices were from Sandoz, Inc. ("Sandoz"); Amneal Pharmaceuticals LLC ("Amneal"); Watson Laboratories, Inc. ("Watson"); Roxane Laboratories, Inc. ("Roxane"); Mylan Pharmaceuticals, Inc. ("Mylan"); and Actavis Elizabeth LLC and Actavis Inc. (collectively, "Actavis"). Since filing suit against these ANDA filers, along with API suppliers Johnson Matthey Inc. and Johnson Matthey Pharmaceuticals Materials (collectively "Johnson Matthey"), Shire has been engaged in a consolidated patent infringement litigation in the US District Court for the District of New Jersey against the aforementioned parties (except Watson, who withdrew their ANDA).

On June 23, 2014, the US District Court for the District of New Jersey granted Shire's summary judgment motion holding that 18 claims of the patents-in-suit were both infringed and valid. The ruling prevents all of the ANDA filers (Sandoz, Roxane, Amneal, Actavis and Mylan) from launching generic versions of VYVANSE until the earlier of either a successful appeal to the US Court of Appeals for the Federal Circuit ("CAFC"), or the expiration of these patents in 2023. To appeal successfully, the ANDA-defendants must overturn the court's rulings for each of these 18 patent claims. All of the defendants have appealed the court's summary judgment ruling to the CAFC. Oral argument occurred on May 6, 2015 and a decision is pending.

### *LIALDA*

In May 2010, Shire was notified that Zydus Pharmaceuticals USA, Inc. ("Zydus") had submitted an ANDA under the Hatch-Waxman Act seeking permission to market a generic version of LIALDA. Within the requisite 45 day period, Shire filed a lawsuit in the US District Court for the District of Delaware against Zydus and Cadila Healthcare Limited, doing business as Zydus Cadila. A Markman hearing took place on January 29, 2015 and a Markman ruling was issued on July 28, 2015. The previously scheduled trial date has been vacated; at present, there is no trial date.

In February 2012, Shire was notified that Osmotica Pharmaceutical Corporation ("Osmotica") had submitted an ANDA under the Hatch-Waxman Act seeking permission to market a generic version of LIALDA. Within the requisite 45 day period, Shire filed a lawsuit in the US District Court for the Northern District of Georgia against Osmotica. A Markman hearing took place on August 22, 2013 and a Markman ruling was issued on September 25, 2014. The Court issued an Order on February 27, 2015 in which all dates in the scheduling order have been stayed.

In March 2012, Shire was notified that Watson Laboratories Inc.-Florida had submitted an ANDA under the Hatch-Waxman Act seeking permission to market a generic version of LIALDA. Within the requisite 45 day period, Shire filed a lawsuit in the US District Court for the Southern District of Florida against Watson Laboratories Inc.-Florida and Watson Pharmaceuticals, Inc. Watson Pharma, Inc. and Watson Laboratories, Inc. were subsequently added as defendants. A trial took place in April, 2013 and on May 9, 2013 the trial court issued a decision finding that the proposed generic product infringes the patent-in-suit and that the patent is not invalid. Watson appealed the trial court's ruling to the CAFC and a hearing took place on December 2, 2013. The ruling of the CAFC was issued on March 28, 2014 overruling the trial court on the interpretation of two claim terms and remanding the case for further proceedings. Shire petitioned the Supreme Court for a writ of certiorari, which was granted on January 26, 2015. The Supreme Court also vacated the CAFC decision and remanded the case to the CAFC for further consideration in light

of the Supreme Court's recent decision in *Teva v Sandoz*. On June 3, 2015, the CAFC reaffirmed their previous decision to reverse the district court's claims construction. We expect the CAFC to issue a mandate in the near future remanding the case to the US District Court for the Southern District of Florida.

In April 2012, Shire was notified that Mylan had submitted an ANDA under the Hatch-Waxman Act seeking permission to market a generic version of LIALDA. Within the requisite 45 day period, Shire filed a lawsuit in the US District Court for the Middle District of Florida against Mylan. A Markman hearing took place on December 22, 2014. A Markman ruling was issued on March 23, 2015. A trial is scheduled during the court's trial term beginning on September 1, 2015.

In March 2015, Shire was notified that Amneal had submitted an ANDA under the Hatch-Waxman Act seeking permission to market a generic version of LIALDA. Within the requisite 45 day period, Shire filed a lawsuit in the US District Court for the District of New Jersey against Amneal, Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Co. India Pvt. Ltd. No trial date has been set.

### *Investigation related to DERMAGRAFT*

The Department of Justice, including the US Attorney's Office for the Middle District of Florida, Tampa Division and the US Attorney's Office for Washington, DC, is conducting civil and criminal investigations into the sales and marketing practices of Advanced BioHealing Inc. ("ABH") relating to DERMAGRAFT.

Following the disposal of the DERMAGRAFT business in January 2014, Shire has retained certain legacy liabilities including any liability that may arise from this investigation. Shire is cooperating fully with these investigations. Shire is not in a position at this time to predict the scope, duration or outcome of these investigations.

### *Civil Investigative Demand relating to VANCOCIN*

On April 6, 2012, ViroPharma received a notification that the United States Federal Trade Commission ("FTC") is conducting an investigation into whether ViroPharma had engaged in unfair methods of competition with respect to VANCOCIN. On August 3, 2012, and September 8, 2014, ViroPharma and Shire respectively received Civil Investigative Demands from the FTC requesting additional information related to this matter. Shire intends to continue to cooperate fully with the FTC investigation. At this time, Shire is unable to predict the outcome or duration of this investigation.

### *Lawsuit related to supply of ELAPRASE to certain patients in Brazil*

On September 24, 2014 Shire's Brazilian affiliate, Shire Farmaceutica Brasil Ltda, was served with a lawsuit brought by the State of Sao Paulo and in which the Brazilian Public Attorney's office has intervened alleging that Shire is obligated to provide certain medical care including ELAPRASE for an indefinite period at no cost to patients who participated in ELAPRASE clinical trials in Brazil, and seeking recoupment to the Brazilian government for amounts paid for these patients to date, and moral damages associated with these claims. Shire intends to defend itself against these allegations but is not able to predict the outcome or duration of this case.

## 16. Accumulated Other Comprehensive loss

The changes in accumulated other comprehensive loss, net of their related tax effects, in the six months to June 30, 2015 and 2014 are included below:

<b>As at June 30, 2015</b>	<b>Foreign currency translation adjustment \$M</b>	<b>Unrealized holding loss on available-for- sale securities \$M</b>	<b>Accumulated other comprehensive loss \$M</b>
As at January 1, 2015	(25.7)	(5.8)	(31.5)
Current period change:			
Net current period other comprehensive (loss)/income	(83.3)	3.3	(80.0)
As at June 30, 2015	(109.0)	(2.5)	(111.5)



As at June 30, 2014	Foreign currency translation adjustment \$M	Unrealized holding gain/(loss) on available-for- sale securities \$M	Accumulated other comprehensive income \$M
As at January 1, 2014	110.4	(0.2)	110.2
Current period change:			
Other comprehensive income before reclassification	10.2	6.9	17.1
Gain transferred to the income statement (within Other income, net) on disposal of available-for- sale securities	-	(3.2)	(3.2)
Net current period other comprehensive income	10.2	3.7	13.9
As at June 30, 2014	120.6	3.5	124.1

## 17. Financial instruments

### Treasury policies and organization

The Group's principal treasury operations are coordinated by its corporate treasury function. All treasury operations are conducted within a framework of policies and procedures approved annually by the Board. As a matter of policy, the Group does not undertake speculative transactions that would increase its currency or interest rate exposure.

### Interest rate risk

The Group is principally exposed to interest rate risk on borrowings under its \$2,100 million RCF, its \$400 million 2013 Facilities Agreement, its \$850 million 2015 Facility Agreement and its Credit lines, on which interest is set at floating rates, to the extent any of these facilities are utilized. At June 30, 2015 the Group had fully utilized the 2013 Facilities Agreement, fully utilized the 2015 Facility Agreement, utilized \$920 million of the RCF and utilized \$50million of its Credit lines. Shire's exposure under its 2013 Facilities Agreement, 2015 Facility Agreement, RCF and Credit lines is to US dollar interest rates.

The Group has evaluated the interest rate risk on the Credit lines, the RCF, the 2013 Facilities Agreement and the 2015 Facility Agreement and considers the risks associated with floating interest rates on borrowings under its facilities as appropriate. A hypothetical one percentage point increase or decrease in the interest rates applicable to drawings under the Credit lines, the 2013 Facilities Agreement, 2015 Facility Agreement and RCF at June 30, 2015 would increase interest expense by approximately \$23 million per annum or would decrease the interest expense by approximately \$5 million per annum.

The Group is also exposed to interest rate risk on its restricted cash, cash and cash equivalents and on foreign exchange contracts on which interest is set at floating rates. This exposure is primarily limited to US dollar, Pounds sterling and Euro interest rates. As the Group maintains all of its cash, liquid investments and foreign exchange contracts on a short term basis for liquidity purposes, this risk is not actively managed. In the six months to June 30, 2015 the average interest rate received on cash and liquid investments was less than 1% per annum. The largest proportion of these cash and liquid investments was in US dollar term deposits with banks.

No derivative instruments were entered into during the six months to June 30, 2015 to manage interest rate exposure. The Group continues to review its interest rate risk and the policies in place to manage the risk.

### Credit risk

Financial instruments that potentially expose Shire to concentrations of credit risk consist primarily of short-term cash investments, derivative contracts and trade accounts receivable (from product sales and from third parties from which the Group receives royalties). Cash is invested in short-term money market instruments, including money market and

liquidity funds and bank term deposits. The money market and liquidity funds in which Shire invests are all triple A rated by both Standard and Poor's and by Moody's credit rating agencies.

The Group is exposed to the credit risk of the counterparties with which it enters into bank term deposit arrangements and derivative instruments. The Group limits this exposure through a system of internal credit limits which vary according to ratings assigned to the counterparties by the major rating agencies. The internal credit limits are approved by the Board and exposure against these limits is monitored by the corporate treasury function. The counterparties to these derivatives contracts are major international financial institutions.

The Group's revenues from product sales in the US are mainly governed by agreements with major pharmaceutical wholesalers and relationships with other pharmaceutical distributors and retail pharmacy chains. For the year to December 31, 2014 there were three customers in the US that accounted for 47% of the Group's product sales. However, such customers typically have significant cash resources and as such the risk from concentration of credit is considered acceptable. The Group has taken positive steps to manage any credit risk associated with these transactions and operates clearly defined credit evaluation procedures. However, an inability of one or more of these wholesalers to honor their debts to the Group could have an adverse effect on the Group's financial condition and results of operations.

A substantial portion of the Group's accounts receivable in countries outside of the United States is derived from product sales to government-owned or government-supported healthcare providers. The Group's recovery of these accounts receivable is therefore dependent upon the financial stability and creditworthiness of the relevant governments. In recent years global and national economic conditions have negatively affected the growth, creditworthiness and general economic condition of certain markets in which the Group operates. As a result, in some countries outside of the US, specifically, Argentina, Greece, Italy, Portugal and Spain (collectively the "Relevant Countries") the Group is experiencing delays in the remittance of receivables due from government-owned or government-supported healthcare providers. The Group continued to receive remittances in relation to government-owned or government-supported healthcare providers in the Relevant Countries in the six months to June 30, 2015, including receipts of \$58.8 million and \$39.6 million in respect of Spanish and Italian receivables, respectively. The Group's exposure to Greece, both in terms of gross accounts receivable and annual revenues, is not material.

To date the Group has not incurred material losses on accounts receivable in the Relevant Countries, and continues to consider that such accounts receivable are recoverable. The Group will continue to evaluate all its accounts receivable for potential collection risks and has made provision for amounts where collection is considered to be doubtful. If the financial condition of the Relevant Countries or other Eurozone countries suffer significant deterioration, such that their ability to make payments becomes uncertain, or if one or more Eurozone member countries withdraws from the Euro, additional allowances for doubtful accounts may be required, and losses may be incurred, in future periods. Any such loss could have an adverse effect on the Group's financial condition and results of operations.

### **Foreign exchange risk**

The Group trades in numerous countries and as a consequence has transactional and translational foreign exchange exposures.

Transactional exposure arises where transactions occur in currencies different to the functional currency of the relevant subsidiary. The main trading currencies of the Group are the US dollar, Pounds Sterling, Swiss Franc, Canadian dollar and the Euro. It is the Group's policy that these exposures are minimized to the extent practicable by denominating transactions in the subsidiary's functional currency.

Where significant exposures remain, the Group uses foreign exchange contracts (being spot, forward and swap contracts) to manage the exposure for balance sheet assets and liabilities that are denominated in currencies different to the functional currency of the relevant subsidiary. These assets and liabilities relate predominantly to inter-company financing. The foreign exchange contracts have not been designated as hedging instruments. Cash flows from derivative instruments are presented within net cash provided by operating activities in the consolidated cash flow statement, unless the derivative instruments are economically hedging specific investing or financing activities.

Translational foreign exchange exposure arises on the translation into US dollars of the financial statements of non-US dollar functional subsidiaries.

At June 30, 2015 the Group had 31 swap and forward foreign exchange contracts outstanding to manage currency risk. The swap and forward contracts mature within 90 days. The Group did not have credit risk related contingent features or collateral linked to the derivatives. The Group has master netting agreements with a number of counterparties to these foreign exchange contracts and on the occurrence of specified events, the Group has the ability to terminate contracts and settle them with a net payment by one party to the other. The Group has elected to present derivative assets and derivative liabilities on a gross basis in the consolidated balance sheet. As at June 30,

2015 the potential effect of rights of set-off associated with the foreign exchange contracts would be an offset to both assets and liabilities of \$0.2 million, resulting in net derivative assets and derivative liabilities of \$7.7 million and \$0.1 million, respectively. Further details are included below:

		Fair value June 30, 2015 \$'M	Fair value December 31, 2014 \$'M
Assets	Prepaid expenses and other current assets	7.9	12.6
Liabilities	Other current liabilities	0.3	7.8

Net gains (both realized and unrealized) arising on foreign exchange contracts have been classified in the consolidated statements of income as follows:

		Location of net gains recognized in income	Amount of net gains recognized in income	
In the six months to			June 30, 2015 \$'M	June 30, 2014 \$'M
Foreign exchange contracts	Other income, net		21.3	13.9

These net foreign exchange gains are offset within Other income, net by net foreign exchange (losses)/gains arising on the balance sheet items that these contracts were put in place to manage.

## 18. Fair value measurement

*Assets and liabilities that are measured at fair value on a recurring basis*

As at June 30, 2015 and December 31, 2014 the following financial assets and liabilities are measured at fair value on a recurring basis using quoted prices in active markets for identical assets (Level 1); significant other observable inputs (Level 2); and significant unobservable inputs (Level 3).

	Carrying value and Fair value			
	Total \$'M	Level 1 \$'M	Level 2 \$'M	Level 3 \$'M
<b>At June 30, 2015</b>				
Financial assets:				
Available-for-sale securities <sup>(1)</sup>	16.3	16.3	-	-
Contingent consideration receivable <sup>(2)</sup>	16.7	-	-	16.7
Foreign exchange contracts	7.9	-	7.9	-
Financial liabilities:				
Foreign exchange contracts	0.3	-	0.3	-
Contingent consideration payable <sup>(3)</sup>	464.7	-	-	464.7

At December 31, 2014	Total \$'M	Level 1 \$'M	Level 2 \$'M	Level 3 \$'M
Financial assets:				
Available-for-sale securities <sup>(1)</sup>	13.1	13.1	-	-
Contingent consideration receivable <sup>(2)</sup>	15.9	-	-	15.9
Foreign exchange contracts	12.6	-	12.6	-
Financial liabilities:				
Foreign exchange contracts	7.8	-	7.8	-
Contingent consideration payable <sup>(3)</sup>	629.9	-	-	629.9

(1) Available-for-sale securities are included within Investments in the consolidated balance sheet.

(2) Contingent consideration receivable is included within Prepaid expenses and other current assets and Other non-current assets in the consolidated balance sheet.

(3) Contingent consideration payable is included within Other current liabilities and Other non-current liabilities in the consolidated balance sheet.

Certain estimates and judgments were required to develop the fair value amounts. The fair value amounts shown above are not necessarily indicative of the amounts that the Group would realize upon disposition, nor do they indicate the Group's intent or ability to dispose of the financial instrument.

The following methods and assumptions were used to estimate the fair value of each material class of financial instrument:

- Available-for-sale securities – the fair values of available-for-sale securities are estimated based on quoted market prices for those investments.
- Contingent consideration receivable – the fair value of the contingent consideration receivable has been estimated using the income approach (using a probability weighted discounted cash flow method).
- Foreign exchange contracts – the fair values of the swap and forward foreign exchange contracts have been determined using an income approach based on current market expectations about the future cash flows.
- Contingent consideration payable – the fair value of the contingent consideration payable has been estimated using the income approach (using a probability weighted discounted cash flow method).

#### *Assets and Liabilities Measured at Fair Value on a Recurring Basis Using Significant Unobservable Inputs (Level 3)*

The change in the fair value of the Group's contingent consideration receivable and payables, which are measured at fair value on a recurring basis using significant unobservable inputs (Level 3), are as follows:

#### **Contingent consideration receivable**

	2015 \$'M	2014 \$'M
Balance at January 1,	15.9	36.1
Initial recognition of contingent consideration receivable	-	33.6
Gain/(loss) recognized in the income statement (within Gain on sale of product rights) due to change in fair value during the period	8.6	(3.3)
Reclassification of amounts to Other receivables within Other current assets	(9.1)	(8.7)
Amounts recorded to other comprehensive income (within foreign currency translation adjustments)	1.3	(0.2)
Balance at June 30,	16.7	57.5

## Contingent consideration payable

	2015 \$'M	2014 \$'M
Balance at January 1,	629.9	405.9
Initial recognition of contingent consideration payable	92.1	174.0
Change in fair value during the period with the corresponding adjustment recognized (within Integration and acquisition costs) in the income statement	(255.7)	21.4
Reclassification of amounts to Other current liabilities	(4.1)	(10.9)
Change in fair value during the period with corresponding adjustment to the associated intangible asset	(0.2)	1.4
Amounts recorded to other comprehensive income (within foreign currency translation adjustments)	2.7	-
Balance at June 30,	464.7	591.8

Of the \$464.7 million of contingent consideration payable as at June 30, 2015 \$19.5 million is recorded within other current liabilities and \$445.2 million is recorded within other non-current liabilities in the Group's balance sheet.

### *Quantitative Information about Assets and Liabilities Measured at Fair Value on a Recurring Basis Using Significant Unobservable Inputs (Level 3)*

Quantitative information about the Group's recurring Level 3 fair value measurements is included below:

#### Financial assets:

#### Fair Value at the Measurement Date

#### At June 30, 2015

	Fair value	Valuation Technique	Significant unobservable Inputs	Range
	\$'M			
Contingent consideration receivable ("CCR")	16.7	Income approach (probability weighted discounted cash flow)	<ul style="list-style-type: none"> <li>• Probability weightings applied to different sales scenarios</li> <li>• Future forecast consideration receivable based on contractual terms with purchaser</li> <li>• Assumed market participant discount rate</li> </ul>	<ul style="list-style-type: none"> <li>• 10 to 70%</li> <li>• \$28.5 million to \$36 million</li> <li>• 8.7%</li> </ul>

Financial liabilities:  At June 30, 2015	Fair Value at the Measurement Date			
	Fair value  \$'M	Valuation Technique	Significant unobservable Inputs	Range
Contingent consideration payable	464.7	Income approach (probability weighted discounted cash flow)	<ul style="list-style-type: none"> <li>• Cumulative probability of milestones being achieved</li> <li>• Assumed market participant discount rate</li> <li>• Periods in which milestones are expected to be achieved</li> <li>• Forecast quarterly royalties payable on net sales of relevant products</li> </ul>	<ul style="list-style-type: none"> <li>• 4 to 85%</li> <li>• 0.9 to 10.5%</li> <li>• 2015 to 2030</li> <li>• \$0.2 to \$7.6 million</li> </ul>

The Group re-measures the CCR (relating to contingent consideration due to the Group following divestment of certain of the Group's products) at fair value at each balance sheet date, with the fair value measurement based on forecast cash flows, over a number of scenarios which vary depending on the expected performance outcome of the products following divestment. The forecast cash flows under each of these differing outcomes have been included in probability weighted estimates used by the Group in determining the fair value of the CCR.

Contingent consideration payable represents future milestones the Group may be required to pay in conjunction with various business combinations and future royalties payable as a result of certain business combinations and licenses. The amount ultimately payable by Shire in relation to business combinations is dependent upon the achievement of specified future milestones, such as the achievement of certain future development, regulatory and sales milestones. The Group assesses the probability, and estimated timing, of these milestones being achieved and re-measures the related contingent consideration to fair value each balance sheet date. The amount of contingent consideration which may ultimately be payable by Shire in relation to future royalties is dependent upon future net sales of the relevant products over the life of the royalty term. The Group assesses the present value of forecast future net sales of the relevant products and re-measures the related contingent consideration to fair value each balance sheet date.

The fair value of the Group's contingent consideration receivable and payable could significantly increase or decrease due to changes in certain assumptions which underpin the fair value measurements. Each set of assumptions and milestones is specific to the individual contingent consideration receivable or payable. The assumptions include, among other things, the probability and expected timing of certain milestones being achieved, the forecast future net sales of the relevant products and related future royalties payable, the probability weightings applied to different sales scenarios of the Group's divested products and forecast future royalties receivable under scenarios developed by the Group, and the discount rates used to determine the present value of contingent future cash flows. The Group regularly reviews these assumptions, and makes adjustments to the fair value measurements as required by facts and circumstances.

#### Assets Measured at Fair Value on a Non-Recurring Basis using Significant Unobservable Inputs (Level 3)

In the six months to June 30, 2015 the Group reviewed its SHP625 and SHP608 IPR&D intangible assets for impairment and recognized an impairment charge of \$523.3 million, recorded within R&D in the consolidated income

statement, to write-down these IPR&D assets to their fair value. The fair value of these IPR&D assets was determined using the income approach, which used significant unobservable (Level 3) inputs. These unobservable inputs included, among other things, the probabilities of these IPR&D assets receiving regulatory approval, the timeframe for such approval, risk-adjusted forecast future cash flows to be generated by these IPR&D assets and the determination of an appropriate discount rate to be applied in calculating the present value of forecast future cash flows. The fair value of these IPR&D assets, determined at the time of the impairment review, was \$120.4 million.

### Fair Value at the Measurement Date

At June 30, 2015	Fair value	Valuation Technique	Significant unobservable Inputs	Range
	\$'M			
IPR&D intangible assets (SHP625 and SHP608)	\$120.4	Income approach (discounted cash flow)	<ul style="list-style-type: none"> <li>• Probability of regulatory approval being obtained</li> <li>• Expected commercial launch date</li> <li>• Assumed market participant discount rate</li> </ul>	<ul style="list-style-type: none"> <li>• 5 to 33%</li> <li>• 2018 to 2021</li> <li>• 9.7 to 10.7%</li> </ul>

The carrying amounts of other financial assets and liabilities materially approximate to their fair value either because of the short-term maturity of these amounts or because there have been no significant changes since the asset or liability was last re-measured to fair value on a non-recurring basis.

## 19. Earnings per share

The following table reconciles net income and the weighted average ordinary shares outstanding for basic and diluted earnings per share for the periods presented:

	<b>6 months to June 30, 2015 \$'M</b>	<b>6 months to June 30, 2014 \$'M</b>
Income from continuing operations, net of taxes	577.0	781.4
Loss from discontinued operations	(7.0)	(27.9)
Numerator for basic and diluted earnings per share	570.0	753.5
Weighted average number of shares:		
	Millions	Millions
Basic <sup>(1)</sup>	589.8	585.3
Effect of dilutive shares:		
Share-based awards to employees <sup>(2)</sup>	3.2	5.0
Diluted	593.0	590.3

(1) Excludes shares purchased by the EBT and presented by Shire as treasury stock.

(2) Calculated using the treasury stock method.

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

	<b>6 months to June 30, 2015 No. of shares Millions</b>	<b>6 months to June 30, 2014 No. of shares Millions</b>
Share-based awards to employees <sup>(1)</sup>	3.2	1.2

(1) Certain stock options have been excluded from the calculation of diluted EPS because (a) their exercise prices exceeded Shire plc's average share price during the calculation period or (b) the required performance conditions were not satisfied as at the balance sheet date.

## 20. Segmental reporting

Shire comprises a single operating and reportable segment engaged in the research, development, licensing, manufacturing, marketing, distribution and sale of innovative specialist medicines to meet significant unmet patient needs.

This segment is supported by several key functions: a Pipeline group, consisting of R&D and Corporate Development, which prioritizes its activities towards late-stage development programs across a variety of therapeutic areas, while focusing its pre-clinical development activities primarily in Rare Diseases; a Technical Operations group responsible for the Group's global supply chain; and an In-line marketed products group which focuses on commercialized



products. The In-Line marketed products group has commercial units that focus exclusively on the commercial execution of its marketed products including in the areas of Rare Diseases, Neuroscience, and Gastrointestinal (“GI”) and Internal Medicine, and to support the development of our pipeline candidates, in Ophthalmics. This ensures that the Group provides innovative treatments, and services the needs of its customers and patients, as efficiently as possible. The business is also supported by a simplified, centralized corporate function group. None of these functional groups meets all of the criteria to be an operating segment.

This single operating and reportable segment is consistent with the financial information regularly reviewed by the Executive Committee (which is Shire’s chief operating decision maker) for the purposes of evaluating performance, allocating resources, and planning and forecasting future periods.

In the periods set out below, revenues by major product were as follows:

6 months to	June 30, 2015 \$'M	June 30, 2014 \$'M
VYVANSE	841.6	710.7
LIALDA/MEZAVANT	306.4	272.5
CINRYZE	286.9	215.5
ELAPRASE	271.5	280.7
REPLAGAL	214.4	244.8
FIRAZYR	196.6	163.9
ADDERALL XR	181.7	184.9
VPRIV	171.1	176.6
PENTASA	145.0	135.5
FOSRENOL	89.2	88.1
GATTEX/REVESTIVE	52.2	-
XAGRID	48.1	55.0
INTUNIV	26.9	182.3
NATPARA	5.9	-
Other product sales	61.9	67.2
Total product sales	2,899.4	2,777.7

## 21. Taxation

The effective rate of tax for the six months to June 30, 2015 was 2% (2014: -19%).

The effective rate of tax for the six months to June 30, 2015 is low primarily due to the reduction in deferred tax liabilities in relation to the impairment of IPR&D intangible assets, the re-measurement of uncertain tax positions relating to ongoing tax audits and the release of certain valuation allowances all recognized during the first half.

The effective rate of tax in the six months to June 30, 2014 was negative primarily due to the recognition of a net tax credit in the first half of 2014 in relation to the settlement of tax positions with the Canadian revenue authorities.

## 22. Related parties

Shire considers that ArmaGen, Inc. (“ArmaGen”) is a related party by virtue of a combination of Shire’s equity stake in ArmaGen and the worldwide licensing and collaboration agreement between the two parties to develop and commercialize AGT-182. In the six months to June 30, 2015 Shire paid \$2.5 million in cash to ArmaGen in exchange for an additional equity stake in ArmaGen, following which Shire holds approximately 21% of ArmaGen’s issued equity. In addition, Shire recorded R&D costs arising from the licensing and collaboration arrangement of \$5.9 million in the first half of 2015, of which \$5.4 million was accrued and unpaid as at June 30, 2015.

## Non GAAP Measures

This Half Yearly Report contains financial measures not prepared in accordance with US GAAP. These measures are referred to as “Non GAAP” measures and include: *Non GAAP net cash/(debt)* and *Non GAAP EBITDA*. These Non GAAP measures exclude the effect of certain cash and non-cash items that Shire's management believes are not related to the core performance of Shire's business.

These Non GAAP financial measures are used by Shire's management to make operating decisions because they facilitate internal comparisons of Shire's performance to historical results and to competitors' results. Shire's Remuneration Committee uses certain key Non GAAP measures when assessing the performance and compensation of employees, including Shire's directors.

The Non GAAP measures are presented in this Half Yearly Report as Shire's management believe that they will provide investors with a means of evaluating, and an understanding of how Shire's management evaluates, Shire's performance and results on a comparable basis that is not otherwise apparent on a US GAAP basis, since many non-recurring, infrequent or non-cash items that Shire's management believe are not indicative of the core performance of the business may not be excluded when preparing financial measures under US GAAP.

These Non GAAP measures should not be considered in isolation from, as substitutes for, or superior to financial measures prepared in accordance with US GAAP.

Where applicable the following items, including their tax effect, have been excluded when calculating Non GAAP EBITDA for both 2015 and 2014:

### *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).

### *Other:*

- Net income tax credit (being income tax, interest and estimated penalties) related to the settlement of certain tax positions with the Canadian revenue authorities;
- Costs associated with AbbVie's terminated offer for Shire, including costs of employee retention awards; and
- Break fee received in relation to AbbVie's terminated offer for Shire.

Growth at CER, which is a Non GAAP measure, is computed by restating 2015 results using average 2014 foreign exchange rates for the relevant period. Average exchange rates used by Shire for the six months to June 30, 2015 were \$1.53:£1.00 and \$1.13:€1.00 (2014: \$1.67:£1.00 and \$1.37:€1.00).

The following table reconciles US GAAP net income to Non GAAP EBITDA:

	<b>6 months to June 30,</b>	
	<b>2015</b>	2014
	<b>\$M</b>	\$M
<b>US GAAP Net Income</b>	<b>570.0</b>	753.5
(Deduct) / add back:		
Loss from discontinued operations, net of tax	<b>7.0</b>	27.9
Equity in (earnings)/losses of equity method investees, net of taxes	<b>0.9</b>	(2.4)
Income taxes	<b>13.3</b>	(125.9)
Other expense/ (income), net	<b>(2.3)</b>	(8.0)
Interest expense	<b>20.9</b>	18.9
Interest income	<b>(2.6)</b>	(19.2)
<b>US GAAP Operating income from continuing operations</b>	<b>607.2</b>	644.8
Amortization	<b>219.6</b>	119.0
Depreciation	<b>72.2</b>	81.5
Asset impairments	<b>523.3</b>	188.0
Acquisition and integration activities	<b>(120.4)</b>	191.2
Divestments, reorganizations and discontinued operations	<b>16.2</b>	55.0
Legal and litigation costs	<b>2.7</b>	3.9
Other	<b>48.0</b>	19.1
<b>Non GAAP EBITDA</b>	<b>1,368.8</b>	1,302.5

## Independent review report to Shire plc

We have been engaged by Shire plc (“the company”) to review the condensed consolidated set of financial statements for the Company and its subsidiaries (the “Group”) in the half-yearly financial report for the six months ended 30 June 2015 which comprises the consolidated balance sheet, consolidated statement of income, consolidated statements of comprehensive income, consolidated statements of changes in equity, the consolidated statements of cash flows and related notes 1 to 22. We have read the other information contained in the half-yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed set of financial statements.

This report is made solely to the company in accordance with International Standard on Review Engagements (UK and Ireland) 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Auditing Practices Board. Our work has been undertaken so that we might state to the company those matters we are required to state to it in an independent review report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company, for our review work, for this report, or for the conclusions we have formed.

### Directors’ responsibilities

The half-yearly financial report is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the half-yearly financial report in accordance with the Disclosure and Transparency Rules of the United Kingdom’s Financial Conduct Authority.

As disclosed in note 1, the annual financial statements of the group are prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”). The condensed set of financial statements included in this half-yearly financial report has been prepared in accordance with the accounting policies the Group intends to use in preparing its next financial statements.

### Our responsibility

Our responsibility is to express to the Company a conclusion on the condensed set of financial statements in the half-yearly financial report based on our review.

### Scope of review

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the condensed set of financial statements in the half-yearly financial report for the six months ended 30 June 2015 is not prepared, in all material respects, in accordance with US GAAP and the Disclosure and Transparency Rules of the United Kingdom’s Financial Conduct Authority.

### Deloitte LLP

Chartered Accountants and Statutory Auditor  
London, United Kingdom  
30 July 2015