

Half-yearly Report

August 5, 2016 – Shire plc (the “Group”) (LSE: SHP, NASDAQ: SHPG), in accordance with the Financial Conduct Authority’s Disclosure and Transparency Rules, is publishing today its Half-yearly Report for the six months ended June 30, 2016.

It should be noted that on August 2, 2016 the Group announced its results for the same period.

Steve Williams
Deputy Company Secretary

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NOTES TO EDITORS

About Shire

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

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

www.shire.com

Shire plc

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

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

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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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2016.

All forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Except to the extent otherwise required by applicable law, we do not undertake any obligation to update or revise forward-looking statements, whether as a result of new information, future events or otherwise.

TRADEMARKS

We own or have rights to trademarks, service marks or trade names that we use in connection with the operation of our business. In addition, our names, logos and website names and addresses are owned by us or licensed by us. We also own or have the rights to copyrights that protect the content of our solutions. Solely for convenience, the trademarks, service marks, trade names and copyrights referred to in this report are listed without the ©, ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks, trade names and copyrights. In addition, this report may include trademarks, service marks or trade names of other companies. Our use or display of other parties' trademarks, service marks, trade names or products is not intended to, and does not imply a relationship with, or endorsement or sponsorship of us by, the trademark, service mark or trade name.

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Chief Executive Officer's review

We are pleased to enclose our financial results for the six-month period ended June 30, 2016. This Half-yearly Report includes unaudited condensed consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP").

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

"The first half of 2016 was marked by a number of important milestones in Shire's history. Chief among them was completion of the combination with Baxalta to create the leading global biotechnology group focused on serving people with rare diseases and highly specialized conditions. While closing this transformative deal and making significant progress on integration, we also delivered double-digit revenue growth, driven by strong contributions from both the legacy Shire and Baxalta businesses.

"Total reported product sales in the first half of 2016 were \$3.9 billion, up 36% against H1 2015, and Non GAAP EBITDA⁽¹⁾ reached \$1.9 billion, growing 35%, inclusive of \$559 million of product sales acquired with Baxalta. We delivered double digit product sales growth across all of Shire's legacy business versus H1 2015: Genetic Diseases up 14% to \$1,301 million, Neuroscience up 19% to \$1,285 million, and Internal Medicine up 18% to \$804 million.

"While closing the Baxalta transaction on June 3, 2016, was certainly the capstone of the first half of the year, it is important to highlight the momentous start of the year with the closing of the acquisition of Dyax on January 22, 2016. As part of the acquisition, we gained global rights to SHP643, a Phase 3, fully humanized monoclonal antibody targeting plasma kallikrein with proof-of-concept Phase 1B efficacy data. These data demonstrated a greater than 90% reduction in Hereditary Angioedema attacks compared to placebo in the 300mg/400mg arms in patients with more than 2 attacks in the three months prior to study entry. If approved globally for the prevention of Type 1 and Type 2 HAE, based on current market analysis, Shire estimates that SHP643 has the potential to generate annual global sales of up to \$2 billion.

"In addition to SHP643, we have advanced a number of key assets in development and have a robust, innovative clinical pipeline with approximately 40 programs for areas of significant unmet medical need. We were extremely pleased to receive FDA approval on July 11, 2016 for XIIDRA, the first FDA-approved treatment for the signs and symptoms of dry eye disease and the first product in our developing franchise in Ophthalmics. We announced positive topline efficacy and safety results for SHP465 in children and adolescents (April 4, 2016) as well as in adults (June 29, 2016) with ADHD. With these study results, we plan on filing a Class 2 resubmission for SHP465 for FDA approval by the end of the year. We also received a positive CHMP opinion for ONIVYDE, and completed the decentralized procedure to support European approval of CUVITRU, expanding therapeutic options within our Immunology portfolio.

"With the remarkable achievements of the first half of 2016, Shire is well positioned to finish the entire year strong. Baxalta integration activities continue to progress very well and, with our new operating structure in place, we have raised our operating synergy expectation by 40% to at least \$700 million in year three post close. This would not have been possible without the commitment of our employees, who have worked tirelessly so that we can continue to deliver best-in-class therapies to patients around the world. We remain resolutely focused on achieving our goals, and I am very confident that Shire will continue to deliver strong growth as we integrate Baxalta and advance our combined portfolio of products."

Flemming Ornskov, M.D., M.P.H.
Chief Executive Officer

(1) Non GAAP earnings before interest, tax, depreciation and amortization ("EBITDA"). The most directly comparable measure under US GAAP is net income (H1 2016: \$256.9m). A reconciliation between US GAAP net income and Non GAAP EBITDA is provided on page 100.

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Business overview for the six months to June 30, 2016

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, 2016 and recent developments

Combination with Baxalta

On June 3, 2016, Shire completed its acquisition of Baxalta, a global innovative biopharmaceutical leader with a sustainable portfolio of differentiated therapies that seek to address unmet medical needs across many disease areas, including hematology, immunology and oncology.

Baxalta's Business

Overview

Baxalta develops, manufactures and markets a diverse portfolio of treatments for hemophilia and other bleeding disorders, immune deficiencies, alpha-1 antitrypsin deficiency, burns and shock, and other chronic and acute medical conditions, as well as oncology treatments for acute lymphoblastic leukemia. Baxalta has also invested in emerging technology platforms, including gene therapy and biosimilars.

Baxalta's Separation from Baxter International Inc.

Baxalta was incorporated in Delaware on September 8, 2014 in connection with the separation of Baxter International, Inc.'s biopharmaceuticals business from its diversified medical products businesses. The separation from Baxter International, Inc. (“Baxter”) was completed on July 1, 2015 pursuant to which Baxalta became an independent public company as a result of a pro rata distribution by Baxter of 80.5% of Baxalta's common stock to Baxter's shareholders. Baxter retained an approximate 19.5% ownership stake in Baxalta immediately following the distribution. Baxalta common stock began trading “regular way” under the ticker symbol “BXLT” on the New York Stock Exchange on July 1, 2015. Prior to Shire's acquisition of Baxalta, Baxter had disposed of all remaining shares of Baxalta's common stock retained in connection with the separation.

Acquired Products

Baxalta's business consists of a portfolio of products serving patient needs in a variety of ways. Baxalta's therapies — by reference to five categories: Hemophilia, Inhibitor Therapies, Immunoglobulin Therapies, BioTherapeutics and Oncology— are further described below, together with selected details for therapies within each category.

Hemophilia. Hemophilia therapies include:

- **ADVATE.** ADVATE [Antihemophilic Factor (Recombinant), plasma/albumin-free method] is a recombinant antihemophilic factor indicated for use in adults and children with hemophilia A (congenital factor VIII deficiency or classic hemophilia) for control and prevention of bleeding episodes, perioperative management and routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
- **ADYNOVATE.** In November 2015, Baxalta received regulatory approval for ADYNOVATE in the United States. ADYNOVATE is an extended half-life rFVIII treatment for hemophilia A based on ADVATE. ADYNOVATE uses the same manufacturing process as ADVATE and adds a proven technology, PEGylation (a chemical process that prolongs the amount of time a compound remains in circulation, potentially allowing for fewer injections), which Baxalta has exclusively licensed from Nektar Therapeutics. The United States patent covering the composition of matter for this technology has a protected expiry date of 2024, subject to potential patent-term extension as applicable.
- **RECOMBINATE.** RECOMBINATE [Antihemophilic Factor (Recombinant)] is a recombinant antihemophilic factor indicated for use in adults and children with hemophilia A for control and prevention of bleeding episodes, perioperative management and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. RECOMBINATE was Baxalta's first recombinant therapy and was introduced in 1992.

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- *HEMOFIL M.* *HEMOFIL M* [Antihemophilic Factor (Human) Method M, Monoclonal Purified], is indicated in hemophilia A for the prevention and control of hemorrhagic episodes. Antihemophilic factor (AHF) is a protein found in normal plasma which is necessary for clot formation. The administration of HEMOFIL M provides an increase in plasma levels of AHF and can temporarily correct the coagulation defect of patients with hemophilia A.
- *IMMUNATE.* Immunate is a highly purified, double virus inactivated, plasma derived Factor VIII/von Willebrand Factor complex concentrate, suitable for the treatment of hemophilia A and von Willebrand disease with FVIII deficiency.
- *IMMUNINE.* Immunine Purified Factor IX Concentrate Virus—Inactivated, is indicated for treatment and prophylaxis of bleeding episodes caused by congenital or acquired factor IX deficiency (hemophilia B, or Christmas disease, hemophilia B with factor IX inhibitors, and acquired factor IX deficiency due to spontaneous development of factor IX inhibitors).
- *RIXUBIS.* RIXUBIS [Coagulation Factor IX (Recombinant)] was launched in the United States in 2013 for the treatment of hemophilia B. RIXUBIS is an injectable medicine used to replace clotting factor IX that is missing in people with hemophilia B.
- *PROTHROMPLEX TOTAL.* PROTHROMPLEX TOTAL is a powder and solvent for solution for injection containing human prothrombin complex and is indicated in adults for the treatment and perioperative prophylaxis of bleeding in acquired deficiency of prothrombin complex coagulation factors, as well as for the treatment and perioperative prophylaxis of hemorrhages in congenital deficiency of vitamin K-dependent coagulation factors when purified specific coagulation factor concentrate is not available.

Inhibitor Therapies. Inhibitor Therapies products are:

- *FEIBA.* FEIBA [Anti-Inhibitor Coagulant Complex] is a plasma-based inhibitor bypass therapy, and is a leading plasma-derived inhibitor management therapy. FEIBA is indicated for use in hemophilia A and hemophilia B patients with inhibitors for control of spontaneous bleeding episodes, to cover surgical interventions and routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
- *OBIZUR.* OBIZUR [Antihemophilic Factor (Recombinant), Porcine Sequence] is an acquired hemophilia A therapy that consists of a recombinant porcine factor VIII.

Immunoglobulin Therapies. Immunoglobulin Therapies products include:

- *GAMMAGARD LIQUID / KIOVIG.* GAMMAGARD LIQUID [Immune Globulin Intravenous (Human)] is Baxalta's liquid formulation of the antibody-replacement therapy immunoglobulin product. GAMMAGARD LIQUID is used to treat patients with primary immunodeficiency (PID). The most common types of PID result in an inability to make a very important type of protein called antibodies, which help the body fight off infections from bacteria or viruses. GAMMAGARD LIQUID is made from human plasma that is donated by healthy people and contains antibodies collected from these healthy people that replace the missing antibodies in PID patients. GAMMAGARD LIQUID is also indicated as a maintenance therapy for adult patients with Multifocal Motor Neuropathy (MMN) in the U.S., and KIOVIG, the brand name used for GAMMAGARD LIQUID outside of the U.S., is also indicated in the EU as an antibody replacement therapy for certain patients with hypogammaglobulinaemia and for immunomodulation in certain patients with primary immune thrombocytopenia (ITP), Guillain Barre syndrome, Kawasaki disease, and MMN.
- *HYQVIA.* HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] is a product consisting of human normal immunoglobulin (IG) and recombinant human hyaluronidase (licensed from Halozyme). The IG provides the therapeutic effect and the recombinant human hyaluronidase facilitates the dispersion and absorption of the IG administered subcutaneously, increasing its bioavailability. The IG is a 10% solution that is prepared from human plasma consisting of at least 98% immunoglobulin G, which contains a broad spectrum of antibodies. HYQVIA is the only subcutaneous IG treatment for PID patients with a dosing regimen requiring only one infusion up to once per month and one injection site per infusion to deliver a full therapeutic dose of IG. HYQVIA is approved in Europe for use by all patients with PID syndromes

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and myeloma or chronic lymphocytic leukemia (CLL) with severe secondary hypogammaglobulinemia and recurrent infections, and in the United States for adults with PID.

- **GAMMAGARD S/D.** GAMMAGARD S/D [Immune Globulin Intravenous (Human)] is indicated for the treatment of PID in patients two years old and older. GAMMAGARD S/D is also indicated for prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell CLL, treatment of adult patients with chronic idiopathic thrombocytopenic purpura (ITP) to increase platelet count and to prevent and/or control bleeding, and prevention of coronary artery aneurysms associated with Kawasaki Syndrome in pediatric patients.
- **SUBCUVIA.** Subcuvia [Human Normal Immunoglobulin] is a replacement therapy in adults and children with PID syndromes, as well as replacement therapy in myeloma and CLL with severe secondary hypogammaglobulinemia and recurrent infections, that is infused subcutaneously.

BioTherapeutics. BioTherapeutics products include:

- **FLEXBUMIN.** Baxalta's FLEXBUMIN [Albumin (Human)] products are indicated for hypovolemia, hypoalbuminemia due to general causes and burns, and for use during cardiopulmonary bypass surgery as a component of the pump prime, while FLEXBUMIN 25% is also indicated for hypoalbuminemia associated with adult respiratory distress syndrome (ARDS) and nephritis, and hemolytic disease of the newborn (HDN). FLEXBUMIN is the first and only preparation of human albumin to be packaged in a flexible plastic container. The FLEXBUMIN flexible, shatterproof container offers important safety features for hospitals by eliminating risk of glass breakage and affords the ability to infuse without a vented administration set. The lighter weight and reduced space requirements for FLEXBUMIN compared to glass containers of equal volume make Baxalta's FLEXBUMIN products more compatible with hospital inventory storage systems. FLEXBUMIN's product portfolio includes multiple formulations with both 5% in a 250 mL solution and 25% in 50 and 100 mL solutions.
- **BUMINATE.** Baxalta's BUMINATE [Albumin (Human)] products are indicated for hypovolemia, hypoalbuminemia associated with general causes and burns, and use during or prior to cardiopulmonary bypass surgery as a component of the pump prime, while BUMINATE 25% is also indicated for hypoalbuminemia associated with ARDS and nephrosis, and HDN. Baxalta's BUMINATE products offer the same high-quality human albumin as FLEXBUMIN, but packaged in glass bottles as BUMINATE in various concentrations and bottle sizes.
- **ARALAST NP.** ARALAST NP is an alpha1-proteinase inhibitor (Alpha1-PI) indicated for chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). ARALAST NP increases antigenic and functional (anti-neutrophil elastase capacity, or "ANEC") serum levels and antigenic lung epithelial lining fluid (ELF) levels of Alpha1-PI.
- **GLASSIA NP.** GLASSIA NP is also an Alpha1-PI used for adults who have clinically evident emphysema due to severe congenital alpha-1 antitrypsin deficiency. GLASSIA is used to increase ANEC serum levels and antigenic lung ELF levels of Alpha1-PI.
- **CEPROTIN.** CEPROTIN is a protein C concentrate [(Human)] replacement therapy to increase protein C to levels that reduce symptoms by allowing the blood to clot normally. Protein C plays an important part in blood clotting by stopping the blood from clotting when enough clots have been produced. If not corrected, damage from too much clotting can cause death.

Oncology. Baxalta acquired the ONCASPAR (pegaspargase) leukemia product portfolio from Sigma-Tau Finanziaria S.p.A.

- **ONCASPAR.** ONCASPAR is indicated as a component of a multi-agent chemotherapeutic regimen for the first-line treatment of patients with acute lymphoblastic leukemia (ALL) and for the treatment of patients with ALL and hypersensitivity to native forms of L-asparaginase. ONCASPAR is currently approved in the United States as a first line treatment and was recently approved more broadly in the EU for use as a combination therapy for the treatment of ALL in pediatric patients from birth to 18 years as well as adult patients.

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Agreements with Baxter

Prior to the separation, Baxalta and Baxter entered into several agreements to effect the separation and provide a framework for Baxalta's relationship with Baxter after the separation. These agreements, some of which are summarized below, govern the relationship between Baxter and Baxalta subsequent to the completion of the separation and provide for the separation of the assets, employees, liabilities and obligations (including investments, property and employee benefits and tax-related assets and liabilities) attributable to periods prior to, at and after the separation.

- **Separation and Distribution Agreement.** Baxter and Baxalta entered into a separation and distribution agreement which sets forth the agreements between Baxter and Baxalta regarding the principal transactions required to affect Baxalta's separation from Baxter and other agreements governing Baxalta's relationship with Baxter. It also identified assets transferred, liabilities assumed and contracts assigned to each of Baxalta and Baxter as part of the separation, and provided for when and how these transfers, assumptions and assignments were to occur.
- **Transition Services Agreement.** Baxalta and Baxter entered into a transition services agreement prior to the separation pursuant to which Baxalta and Baxter and their respective subsidiaries provide to each other, on an interim, transitional basis, various services, including services to be provided by Baxter such as, among others, finance, information technology, human resources, quality, supply chain and certain other administrative services.
- **Long Term Services Agreement.** Baxter and Baxalta entered into a long term services agreement prior to the separation pursuant to which Baxter and Baxalta and their respective subsidiaries provide to each other certain services at shared facilities following the separation, such as providing utilities and other critical services, the absence of which could disrupt the parties' operations.
- **Tax Matters Agreement.** Baxalta and Baxter entered into a tax matters agreement prior to the distribution which generally governs their respective rights, responsibilities and obligations after the distribution with respect to taxes for any tax period ending on or before the distribution date, as well as tax periods beginning before and ending after the distribution date. In addition, the tax matters agreement addresses the allocation of liability for taxes that were incurred as a result of restructuring activities undertaken to effectuate the distribution and provides for Baxalta to indemnify Baxter against any tax liabilities resulting from Baxalta's action or inaction that causes the merger-related transactions to be taxable. For a description of the potential effect of the combination on the tax status of the separation and related transactions, see section titled "Risk Factors—Risks Related to the Combination with Baxalta" and "the combination with Baxalta could result in significant liability to the Group if the combination causes the spin-off of Baxalta from Baxter or a Later Distribution, as defined below, to be taxable".
- **Manufacturing and Supply Agreement.** Baxalta entered into a manufacturing and supply agreement with Baxter prior to the separation pursuant to which Baxalta or Baxter, as the case may be, manufacture, label, and package products for the other party, such as Baxalta's Flexbumin products. Baxalta's rights to such technology are limited by the terms of the Galaxy license agreement described herein, including with respect to the use of such technology and the physical location and ownership of any such equipment.
- **Galaxy License Agreement.** Baxalta entered into an intellectual property license agreement with Baxter, which we refer to as the Galaxy license agreement, pursuant to which Baxalta received a perpetual, non-transferrable, non-sublicenseable, royalty-free, fully paid, worldwide license to certain intellectual property known as the Galaxy technology in order to allow Baxalta to continue using such technology in its plasma-derived products. This license primarily provides Baxalta with the right to Galaxy trademarks, as well as know-how and trade secrets necessary to operate and maintain (but not to manufacture) equipment using the Galaxy technology.
- **Transitional Trademark License Agreement.** Baxalta and Baxter entered into a transitional trademark license agreement pursuant to which each granted the other a non-exclusive, royalty-free and worldwide license to use certain of each other's trademarks following the separation, with the license granted to Baxter limited to use by Baxter in its performance of its obligations under the separation transaction agreements. The license to Baxalta allows it to continue using certain of Baxter's trademarks (including the Baxter name) in order to provide sufficient time for Baxalta to rebrand or phase out its use of the licensed marks.
- **Employee Matters Agreement.** Baxalta entered into an employee matters agreement with Baxter which allocated assets, liabilities and responsibilities relating to employee compensation and benefit plans and

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programs and other related matters in connection with the separation, including the treatment of outstanding incentive awards and certain retirement and welfare benefit obligations, both in and outside of the United States.

- **International Commercial Operations Agreement.** Baxalta and Baxter entered into an international commercial operations agreement that provided for the conduct of the Baxalta business by Baxter in such countries until the local separation is completed, and provided that Baxalta will be subject to all the risks and burdens of, and will be entitled to all the rewards generated by, the Baxalta business during such period, since the local separation of Baxalta's business in certain countries outside the United States did not occur prior to the separation due to regulatory requirements, the need to obtain consents from local governmental authorities, and other business reasons.

In addition to the foregoing, Baxalta and Baxter also entered into other agreements prior to the separation, including, a shareholder's and registration rights agreement, wherein Baxalta agreed, upon the request of Baxter, to use reasonable best efforts to effect a registration under applicable federal and state securities laws of any shares of Baxalta's common stock retained by Baxter.

Letter Agreement with Baxter and Shire

On January 11, 2016, Baxter, Shire and Baxalta entered into a letter agreement ("Letter Agreement") in connection with the merger, which, among other things, addresses certain aspects of the tax matters agreement and modified certain aspects of the shareholder's and registration rights agreement.

Under the Letter Agreement, from and after the closing of the merger, Baxalta agreed to indemnify, and Shire agreed to guarantee such indemnity to, Baxter and each of its affiliates and each of their respective officers, directors and employees against certain tax-related losses resulting from the merger (other than losses resulting from any disposition of Baxalta common stock by Baxter (i) that are not attributable to the merger and (ii) other than in the initial distribution on July 1, 2015 and certain debt-for-equity exchanges, exchange offers, contribution of Baxalta shares to Baxter's U.S. pension fund or a dividend distribution to Baxter's stockholders (in each case as contemplated by the Letter Agreement)).

In addition, under the Letter Agreement, Shire agreed to cooperate with Baxalta and Baxter to enable Baxalta to comply with its obligations under the shareholder's and registration rights agreement and to use its reasonable best efforts to facilitate Baxter's disposition of Baxalta common stock in certain SEC-registered offerings. Each of Shire and Baxalta agreed in the Letter Agreement not to hold their respective stockholder meetings to approve, and not to consummate, the merger before the earliest of (a) the date that Baxter completed marketing periods for two debt-for-equity exchanges and one equity exchange offer with respect to its Baxalta common stock, (b) the date on which Baxter disposed of all its Baxalta common stock, or (c) June 17, 2016 (subject to tolling or extension (generally to no later than June 25, 2016) under certain circumstances). Prior to Shire's acquisition of Baxalta, Baxter had disposed of all remaining shares of Baxalta's common stock retained in connection with the separation.

Properties

At the time of the acquisition by Shire, Baxalta's global headquarters was located in a 260,000 square foot facility in Bannockburn, Illinois. Baxalta manufactures its products in more than ten manufacturing facilities around the world. Baxalta owns or has long-term leases on all of its manufacturing facilities. Baxalta's principal manufacturing facilities are listed below.

Location	Approximate Sq. Footage	Owned/Leased
Krems, Austria	264,000	Owned(1)
Orth, Austria	654,000	Owned
Vienna, Austria	1,360,000	Owned(2)
Lessines, Belgium	36,000	Leased
Hayward, California	36,000	Leased
Los Angeles, California	448,000	Owned
Thousand Oaks, California	165,000	Owned
Covington, Georgia	1,000,000	Owned(3)
Round Lake, Illinois	53,000	Leased
Pisa, Italy	30,000	Owned
Rieti, Italy	151,000	Owned
Milford, Massachusetts	99,000	Owned
Woodlands, Singapore	150,000	Owned/Leased(4)
Neuchatel, Switzerland	140,000	Owned

(1) Baxalta is expanding its manufacturing facility in Krems, Austria, for production of Hematology products.

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- (2) Baxalta owns several closely-located facilities with manufacturing operations in Vienna, Austria with total square footage of approximately 1,360,000.
- (3) Baxalta is currently building a state-of-the-art manufacturing facility near Covington, Georgia, to support the growth of its plasma-based products.
- (4) Baxalta owns the facility at Woodlands, Singapore, and leases the property upon which it rests.

In 2015, Baxalta opened its global innovation center based in Cambridge, Massachusetts, serving as the headquarters for Research & Development, Oncology, Biosimilars and Business Development.

Baxalta's facility in Hoover, Alabama is a critical facility for the testing of human plasma, including plasma collected by its BioLife subsidiary (as more fully described in the section titled "—Sources and Availability of Raw Materials" below for use in Baxalta's products.

Sources and Availability of Raw Materials

Human plasma is a critical raw material in Baxalta's business. Baxalta owns and operates plasma collection facilities in the United States and Austria through its wholly owned subsidiary BioLife Plasma Services L.P. ("BioLife"). BioLife operates and maintains more than 80 state-of-the-art plasma collection facilities in 24 states throughout the United States and at seven locations in Austria. Baxalta also maintains relationships with other plasma suppliers to ensure that it retains the flexibility to meet market demand for its plasma-based therapies, including through its 10-year (expiring July 2022 unless it renews pursuant to its terms) contract manufacturing agreement with Sanquin Blood Supply Foundation of the Netherlands.

Competition

Baxalta faces substantial competition from pharmaceutical, biotechnology and other companies of all sizes, in the United States and internationally, and such competitors continue to expand their manufacturing capacity and sales and marketing channels. Competition is primarily focused on cost-effectiveness, price, service, product effectiveness and quality, patient convenience and technological innovation. There has been increasing consolidation in Baxalta's customer base, which continues to result in pricing and market pressures.

The principal sources of competition for Baxalta's principal products globally are as follows:

- ADVATE: Xyntha®/ReFacto AF® (Pfizer and Swedish Orphan Biovitrum); Kogenate® (Bayer); Helixate® (CSL Behring); Eloctate® (Biogen Idec); NovoEight® (Novo Nordisk); and Nuwiq® (Octapharma).
- FEIBA: NovoSeven®/NovoSeven RT® (Novo Nordisk); Coagil VII® (Pharmstandard); and Facteur VII-LFB® (LFB Group).
- GAMMAGARD LIQUID: Privigen®/Hizentra®/Carimune NF® (CSL Behring); Flebogamma DIF®/Gamunex-C® (Grifols); Octagam®/Octagam 10®/Gammanorm® (Octapharma); Ig Vena®/Gammaked® (Kedrion); and Intratect 10%®/Intratect, Intraglobin F®/Bivigam® (Biotest).

Additionally, for each of the principal products listed above, there are additional competitive products or alternative therapy regimens available on a more limited geographic basis throughout the world.

Employees

Baxalta employed approximately 17,000 persons as of December 31, 2015. Outside of the United States, some of Baxalta's employees are represented by unions or works councils.

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Other Business Developments

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

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

Acquisition of Dyax

- On January 22, 2016 Shire completed its acquisition of Dyax for upfront cash consideration of \$5.9 billion. With the acquisition, Shire received the global rights to SHP643 (formerly known as DX2930), a Phase 3, fully humanized monoclonal antibody targeting plasma kallikrein with proof-of-concept Phase 1B efficacy data. These data demonstrate a greater than 90% reduction in Hereditary Angioedema (“HAE”) attacks compared to placebo in the 300mg/400mg arms in patients with more than 2 attacks in the 3 months prior to study entry. SHP643 has received Fast Track, Breakthrough Therapy, and Orphan Drug designations by the United States Food and Drug Administration (“FDA”) and has also received Orphan Drug status in the European Union (“EU”). If approved globally for the prevention of Type 1 and Type 2 HAE, based on current market analysis Shire estimates that SHP643 could have the potential to generate annual global sales of up to \$2 billion.

Products

ONIVYDE for the treatment of metastatic pancreatic cancer

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

HYQVIA for the treatment of primary and certain secondary immunodeficiencies

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

XIIDRA for the treatment of Dry Eye Disease

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

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

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

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

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

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BUCCOLAM for the treatment of prolonged, acute, and convulsive seizures in infants, toddlers, children and adolescents

- On February 18, 2016, the FDA granted orphan designation to BUCCOLAM for the treatment of status epilepticus. Further, the FDA advised that they consider status epilepticus a unique indication compared to repetitive seizures.

VYVANSE for the treatment of Attention-Deficit/Hyperactivity Disorder (“ADHD”) and Binge Eating Disorder (“BED”) in adults

- A new drug application has been submitted to the FDA for VYVANSE (lisdexamfetamine dimesylate) as a chewable tablet formulation.
- A marketing application for VYVANSE BED in adults has been filed in Australia.

CINRYZE for the prophylactic treatment of HAE

- CINRYZE was launched in Canada in February 2016.

Pipeline

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

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

SHP607 for the prevention of certain complications of prematurity

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

SHP465 for the treatment of ADHD

- On June 29, 2016, Shire announced positive topline results of the SHP465 efficacy and safety study in adults with ADHD.
- On April 4, 2016, Shire announced positive topline results of the SHP465 safety and efficacy study in children and adolescents aged 6 to 17 years with ADHD. The primary efficacy analysis demonstrated that SHP465 was superior to placebo on the change from baseline in ADHD-RS-IV (“ADHD rating scale”). SHP465 was also superior to placebo in the key secondary efficacy analysis on the clinical global impression improvement scale (“CGI-I”). Adverse events were generally mild-to-moderate in severity and similar to those observed in previous SHP465 studies and with other amphetamine compounds.
- In April 2016, Shire successfully completed a required pharmacokinetics (“PK”) study of SHP465. The PK properties of SHP465 were well characterized in children and adolescents aged 6 to 17 years with ADHD and confirmed the exposure necessary for once-daily oral dosing.
- Shire is on track to file a Class 2 Resubmission of the New Drug Application (“NDA”) for SHP465 with the FDA by the end of 2016.

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SHP625 for the treatment of cholestatic liver disease

- On June 13, 2016, Shire announced that the FDA has granted Breakthrough Therapy Designation for SHP625 (maralixibat) for progressive familial intrahepatic cholestasis type 2.
- In April 2016, Shire received preliminary results from CAMEO, a Phase 2, open-label, noncomparative, 14 week study of SHP625 in adult patients with primary sclerosing cholangitis. The primary objective of the study was to evaluate the safety and tolerability of SHP625 and these safety and tolerability results were consistent with previous SHP625 studies. There were also significant reductions from baseline in serum bile acids and pruritus by ItchRO score, the magnitude of the effect being consistent with what has been observed in SHP625 studies of other patient populations. However, there was no significant reduction from baseline in serum alkaline phosphatase or other liver parameters.

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

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

CUVITRU for the treatment of primary immunodeficiency disorders

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

FIRAZYR for the treatment of HAE in Japan

- In April 2016, Shire received preliminary results from a Phase 3 trial to evaluate the efficacy and safety of FIRAZYR for the acute treatment of angioedema attacks in Japanese patients with HAE. The data demonstrated that the efficacy and safety profile was similar between Japanese patients and those patients who participated in Shire’s previously-conducted Phase 3 program.

Legal Proceedings

See Note 20, Legal and other proceedings, of this Half-yearly Report for details of Shire’s legal proceedings.

Dividend

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

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

⁽¹⁾ Translated using a GBP:USD exchange rate of 1.3202.

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Research and development

Products in Registration

Neuroscience

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 has been completed and submission of the INTUNIV application for Marketing Authorization Application in Japan was made on January 27, 2016.

Internal Medicine

NATPAR/NATPARA for the treatment of HPT

NATPAR is currently under review in Europe as an adjunct to calcium and vitamin D to control hypocalcemia in patients with HPT. NATPARA was approved by the FDA in January 2015.

Hematology

BAX 855 ADYNOVATE/ADYNOVI for the treatment of hemophilia A

BAX 855 is a PEGylated rFVIII, considered as lead candidate of the rFVIII EHL (extended half-life) program. BAX 855 is considered a next-generation ADVATE molecule with improved pharmacokinetic properties, to provide Hemophilia A patients on prophylaxis another option built on the proven ADVATE molecule. Phase 2/3 has been completed, followed by approval and first product launch in the U.S. (fourth quarter of 2015) and then Japan (second quarter of 2016). An application was filed with the European Medicines Agency ("EMA") in March 2016 and the Group received feedback from the EMA in July 2016. Shire is in the process of preparing responses to these questions.

VONVENDI for the treatment of von Willebrand disease

VONVENDI is the first recombinant therapy providing a pure von Willebrand disease ("VWD") factor with customized dosing. Baxalta received U.S. regulatory approval in December 2015 and anticipates the product will be broadly available in the U.S. in late 2016. A surgery clinical trial is ongoing which is required for filing in Europe.

Phase 3 and Phase 3-ready

Genetic Diseases

SHP643 for the treatment of HAE

SHP643 is a Phase 3 novel long-acting highly potent human monoclonal antibody inhibitor of pKal. SHP643 has received Fast Track, Breakthrough Therapy, and Orphan Drug Designations by the FDA and received Orphan Drug Designation in the EU. Shire initiated a Phase 3 clinical trial in the first quarter of 2016.

FIRAZYR (icatibant) for the treatment of acute attacks of HAE in Japan

The final results of the Phase 3 Japan study demonstrated that the efficacy and safety profile of FIRAZYR for the acute treatment of angioedema attacks was similar between Japanese patients and those patients who participated in Shire's previously conducted Phase 3 program. Shire is planning to file a JNDA in 2017 for the indication, treatment of acute attacks of HAE.

SHP609 for the treatment of Hunter syndrome with CNS symptoms

SHP609 is in development as an enzyme replacement therapy ("ERT") delivered intrathecally for the treatment of Hunter syndrome patients with early cognitive impairment. Hunter syndrome is a Lysosomal Storage Disorder. In December 2014 the FDA granted SHP609 Fast Track Designation. In addition, this product has been granted Orphan Drug Designation in the U.S. The Group has initiated a pivotal Phase 2/3 clinical trial which is currently enrolling and an extension study is ongoing.

SHP616 (CINRYZE SC) life cycle management

Shire is pursuing a subcutaneous formulation of CINRYZE for routine prophylaxis against HAE attacks in adolescent and adult patients. An IND was submitted in October 2015, and Shire initiated a Phase 3 study in the first quarter of 2016.

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SHP616 (CINRYZE) for routine prophylaxis and treatment of acute attacks in adolescent and adult patients with HAE in Japan

CINRYZE is indicated in the U.S. 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 with inclusion of self-administration in 2016 and the Phase 3 clinical trial is planned to start enrolling patients the second half of 2016.

Neuroscience

SHP465 for the treatment of ADHD in adults

For details about this program, please see “significant events in the six months to June 30, 2016 and recent developments” above.

LDX for the treatment of ADHD in Japan

LDX, currently marketed as VYVANSE in the U.S. and ELVANSE in certain countries in the EU, for the treatment of ADHD. Shionogi and Shire will co-develop and sell ADHD products in Japan, including LDX. A Phase 2/3 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.

Internal Medicine

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

RESOLOR was approved in 2009 in Europe for use in women for the symptomatic treatment of chronic constipation in whom laxatives fail to provide adequate relief. On June 3, 2015 Shire announced that prucalopride has been approved by the European Commission for use in adults (men and women) for the symptomatic treatment of chronic constipation in whom laxatives fail to provide adequate relief. Shire has discussed with the FDA the requirements for filing an NDA for prucalopride and is currently working towards fulfilling those requirements in anticipation of an NDA submission.

SHP621 Oral Budesonide Suspension (“OBS”), for the treatment of adolescents and adults with EoE

For current developments about this program, please see “significant events in the six months to June 30, 2016 and recent developments” above.

OBS is a proprietary viscous oral formulation of budesonide that is designed to coat the esophagus where the drug can act locally. The FDA has granted Orphan Drug designation to OBS for the treatment of patients with EoE. In addition, on May 31, 2016, the FDA granted SHP621 Breakthrough Therapy Designation. Shire initiated a Phase 3 program for the treatment of adolescents and adults with EoE in the first quarter of 2016.

SHP633 (REVESTIVE) for the treatment of short bowel syndrome (“SBS”) in Japan

REVESTIVE is an approved therapy in the U.S. and Europe to treat adults with SBS who are dependent on parenteral support. A Phase 3 bridging study in adults was initiated in Japan in 2014 and is currently ongoing.

Hematology

OBIZUR (CHAWI SURGERY) for patients with congenital hemophilia A with inhibitors undergoing surgery

OBIZUR is a recombinant porcine sequence FVIII (rpFVIII), from which major parts of the B-domain have been deleted (BDD). OBIZUR is sufficiently similar to human FVIII in promoting hemostasis and for monitoring the FVIII levels and different enough in structure to render it less susceptible to inactivation by circulating inhibitory antibodies to human FVIII. Patients with inhibitors are at risk of perioperative bleeding complications, presenting therapeutic challenges in elective or emergency surgery. The CHAWI surgery clinical protocol was submitted to the Medicines and Healthcare Regulatory Agency (UK) in March 2016 and is ongoing.

Immunology

HYQVIA

Shire is undertaking efforts to expand indications for HYQVIA, including for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy, a neurological disorder characterized by progressive weakness and impaired sensory function in the legs and arms. A Phase 3 clinical trial is underway.

Oncology

SHP616 (CINRYZE) for the treatment of Antibody Mediated Rejection

A Phase 2 study for the treatment of Antibody Mediated Rejection (“AMR”) with SHP616 was completed. Shire has received FDA and EMA feedback and submitted an investigational new drug application (“IND”) in the second

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quarter of 2015. The FDA granted Fast Track designation for SHP616 in October 2015 and Shire began enrollment in a Phase 3 study for the treatment of acute AMR in the second quarter of 2016.

CALASPARGASE PEGOL

In July 2015, Baxalta acquired the ONCASPAR (pegaspargase) product portfolio from Sigma-Tau Finanziaria S.p.A. Through the acquisition, Baxalta gained the investigational biologic calaspargase pegol, which is Baxalta's next generation pegylated asparaginase, currently in Phase 3 development.

Biosimilars

BAX 2200

Baxalta established a collaboration with Coherus Biosciences, Inc. ("Coherus") to develop and commercialize BAX 2200, a biosimilar product candidate for ENBREL® (etanercept), which is indicated for the treatment of autoimmune deficiencies, in Europe, Canada, Brazil and other markets. This is Baxalta's most advanced biosimilar, and, in January 2016, Baxalta announced that it had met its primary end point in its Phase 3 clinical trials for rheumatoid arthritis. There is also a Phase 3 clinical trial ongoing for psoriasis and, in early stage clinical trials, Coherus has demonstrated pharmacokinetic equivalence versus the innovator molecule.

BAX 2923

Baxalta is collaborating with Momenta Pharmaceuticals, Inc. ("Momenta") on the development and commercialization of BAX 2923, a biosimilar product candidate for HUMIRA® (adalimumab). In December 2015, Baxalta announced that BAX 2923 met the primary endpoint in a study evaluating the pharmacokinetics of BAX 2923 compared to both U.S. and EU sourced HUMIRA® reference products in healthy volunteers. Separately, in October 2015, Baxalta initiated a Phase 3 pivotal clinical trial for BAX 2923 in patients with chronic plaque psoriasis.

Phase 2

Genetic Diseases

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 the third quarter of 2010 which has now completed. Shire initiated a Phase 2b clinical trial for SHP610, which is designed to establish clinical proof of concept. An extension study is ongoing. The product has been granted Orphan Drug Designation in the U.S. and in the EU.

Internal Medicine

SHP647 for the treatment of moderate-to-severe inflammatory bowel disease (IBD)

For current developments about this program, please see Other Second Quarter 2016 Developments, above.

SHP626 for the treatment of NASH with liver fibrosis

For current developments about this program, please see Other Second Quarter 2016 Developments, above.

SHP626 is in development for the treatment of NASH. A U.S. Investigational New Drug application was approved by the FDA in the fourth quarter of 2014, and a Phase 1b multiple dose trial has been completed.

SHP625 for the treatment of cholestatic liver disease

For current developments about this program, please see Other Second Quarter 2016 Developments, above.

Shire is currently conducting Phase 2 studies in the following indications: Alagille Syndrome ("ALGS") and Progressive Familial Intrahepatic Cholestasis ("PFIC"). This product has been granted Orphan Drug Designation both in the U.S. and EU.

Ophthalmics

SHP607 for the prevention of certain complications of prematurity

For current developments about this program, please see Other Second Quarter 2016 Developments, above.

SHP640 for the treatment of infectious conjunctivitis

SHP640, a therapy in late-stage development for the treatment of infectious conjunctivitis, an ocular surface condition commonly referred to as pink eye. Shire met with the FDA in the second quarter of 2016 to discuss a program in bacterial conjunctivitis, and has adapted the program plan based on FDA feedback. The program in

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adenoviral conjunctivitis was previously agreed with the FDA in 2015. Based on the feedback from the FDA meeting, Shire intends to initiate the Phase 3 program in the first quarter of 2017.

Immunology

GLASSIA – Alpha-1 Antitrypsin for the treatment of acute Graft-versus-Host Disease (aGvHD)

GLASSIA, a highly purified liquid form of alpha-1 anti-trypsin (A1P1) derived from human plasma, is being evaluated for the treatment of acute Graft-versus-Host Disease (aGvHD) with lower gastrointestinal (GI) involvement as an add-on therapy to steroids in the first-line treatment. The Phase 2/3 study is on schedule to initiate in the fourth quarter of 2016.

SM101 for the treatment of systemic lupus erythematosus

SM101 is an investigational immunoregulatory treatment that has completed Phase 2a studies for systemic lupus erythematosus, a disorder in which the immune system attacks healthy tissue.

Oncology

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

Shire has completed two Phase 2 studies in transplant recipients. This product has been granted Orphan Drug Designation in both the U.S. 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 and additional FDA feedback in November, Shire plans to progress the program into Phase 3 in the second half of 2016.

Imalumab (BAX 069) for the treatment of colorectal cancer

BAX 069 is a monoclonal antibody with a novel mode of action for the treatment of solid tumors, targeting the oxidized form of cytokine macrophage migration inhibitor factor. BAX 069 is currently in Phase 2 clinical trials (colorectal cancer and malignant ascites). Imalumab is a First in Class fully Human anti-oxMIF antibody for the treatment of solid and potentially liquid tumors with favorable safety profile found in Phase 1 solid tumors trial. Imalumab mCRC 3rd Line proof of concept trial opened May 2015; interim read-out planned in the third quarter of 2016 to expedite potential entry into a Phase 3 clinical trial.

ONIVYDE (nal-IRI)

ONIVYDE (nal-IRI) has shown robust efficacy with manageable toxicity in post-gemcitabine metastatic pancreatic cancer patients. ONIVYDE is approved in the U.S. and in Taiwan since October 2015. A positive opinion recommending the marketing authorization for its use in adult patients has been received in the EU with potential for approval in the second half of 2016.

Phase 1

Genetic Diseases

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 U.S. and the EU. The Group initiated a Phase 1/2 clinical trial in the third quarter of 2012. The trial is currently ongoing, but top line interim results were available in late April 2015. Based upon this data, SHP611 appeared to be well tolerated at all doses. Shire is currently enrolling an additional cohort at the highest dose and anticipates the data readout from this cohort to be available in early 2017, which will inform the future strategy for the program.

SHP622 for the treatment of Friedreich’s Ataxia (“FA”)

SHP622 is in development for the treatment of FA. 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 to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of SHP622 in adults with FA has been completed. SHP622 was generally safe and well tolerated when administered as single and multiple PO doses. Shire will continue to analyze these results and determine an optimal path forward for this program.

SHP623 (rc1-INH) for neuromyelitis optica (“NMO”)

rc1-INH is a recombinant C1 inhibitor for the prophylactic treatment of NMO, a type of inflammatory demyelinating disease. The treatment was previously being developed as SHP623 for the prophylactic treatment of HAE. Shire initiated a Phase 1 first-in-human study of SHP623 in the first quarter of 2016 and upon completion of this study it will be developed for the treatment of NMO.

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

Shire has a worldwide licensing and collaboration agreement with ArmaGen for SHP631. 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 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. In July 2016, ArmaGen announced the presentation of data from the first cohort of four adult patients. The data have supported a recommendation by an independent Data Monitoring committee to proceed to the study's second cohort.

Hematology

SHP826 for the treatment of hemophilia A

SHP826 is an investigational, extended half-life rFVIII treatment targeting weekly dosing for hemophilia A patients. The Phase 1 study of SHP826 has commenced.

BAX 930 (ADAMTS13) for the acute treatment and long-term prophylaxis of hereditary thrombotic thrombocytopenic purpura (hTTP)

BAX 930 is a recombinant human ADAMTS13 (rADAMTS13) protein for the acute treatment and long-term prophylaxis of hereditary thrombotic thrombocytopenic purpura (hTTP), a rare, ultra-orphan condition. BAX 930 will be assessed as a replacement therapy for hTTP. Phase 1/2 has been completed, and Phase 3 planning has been initiated.

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Going Concern

As stated in Note 1 to the unaudited 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 consider it appropriate 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, 2016 and June 30, 2015

The financial information contained within the Half-yearly Report has been prepared under US GAAP, being the accounting principles that the Group will prepare or prepared its annual financial statements for the years ended December 31, 2016 and 2015.

Total revenues

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

	3 Months ended June 30,				6 Months ended June 30,			
	2016	2015	change	Non- GAAP CER growth %	2016	2015	change	Non- GAAP CER growth %
	(in millions)		%		(in millions)		%	
Product sales	\$2,322.1	\$1,476.2	+57	+58	\$3,949.4	\$2,899.4	+36	+38
Royalties and other revenues	107.0	81.4	+31	+30	189.0	146.6	+29	+28
Total	\$2,429.1	\$1,557.6	+56	+57	\$4,138.4	\$3,046.0	+36	+37

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Product revenues

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

	3 Months ended June 30,				6 Months ended June 30,			
	2016	2015	Product sales growth %	Non GAAP CER growth %	2016	2015	Product sales growth %	Non GAAP CER growth %
Net product sales:								
(in millions, except percentages)								
Product sales:								
CINRYZE	\$ 173.0	\$ 138.8	+25	+25	\$ 337.2	\$ 286.9	+18	+18
ELAPRASE	154.0	146.5	+5	+8	277.6	271.5	+2	+6
FIRAZYR	136.7	104.1	+31	+31	265.0	196.6	+35	+35
REPLAGAL	118.4	116.9	+1	+1	221.6	214.4	+3	+6
VPRIV	88.0	84.7	+4	+4	171.6	171.1	-	+2
KALBITOR	17.7	-	n/a	n/a	28.1	-	n/a	n/a
Genetic Diseases total	687.8	591.0	+16	+17	1,301.1	1,140.5	+14	+16
VYVANSE	517.7	424.8	+22	+22	1,026.9	841.6	+22	+23
ADDERALL XR	101.8	86.0	+18	+18	200.6	181.7	+10	+11
Other Neuroscience	35.7	21.9	+63	+64	57.8	52.4	+10	+13
Neuroscience total	655.2	532.7	+23	+23	1,285.3	1,075.7	+19	+20
LIALDA/MEZAVANT	193.7	157.9	+23	+23	361.7	306.4	+18	+19
PENTASA	72.9	66.3	+10	+10	136.9	145.0	-6	-6
GATTEX/REVESTIVE	44.5	37.3	+19	+19	96.2	52.2	+84	+85
NATPARA	19.9	5.9	+237	+237	35.5	5.9	+502	+502
Other Internal Medicine	88.7	85.1	+4	+4	173.3	173.7	-	+2
Internal Medicine total	419.7	352.5	+19	+19	803.6	683.2	+18	+18
HEMOPHILIA	275.6	-	n/a	n/a	275.6	-	n/a	n/a
INHIBITOR THERAPIES	74.0	-	n/a	n/a	74.0	-	n/a	n/a
Hematology total	349.6	-	n/a	n/a	349.6	-	n/a	n/a
IMMUNOGLOBULIN THERAPIES	138.2	-	n/a	n/a	138.2	-	n/a	n/a
BIO THERAPEUTICS	51.3	-	n/a	n/a	51.3	-	n/a	n/a
Immunology total	189.5	-	n/a	n/a	189.5	-	n/a	n/a
Oncology total	20.3	-	n/a	n/a	20.3	-	n/a	n/a
Total product sales	\$2,322.1	\$1,476.2	+57	+58	\$3,949.4	\$2,899.4	+36	+38

(1) 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 2016 product sales and revenues restated using 2015 average foreign exchange rates to 2015 actual product sales and revenues. Average exchange rates used by Shire for Q2 2016 were \$1.45:£1.00 and \$1.13:€1.00 (2015: \$1.52:£1.00 and \$1.10:€1.00). Average exchange rates used by Shire for the six months to June 30, 2016 were \$1.44:£1.00 and \$1.11:€1.00 (2015: \$1.53:£1.00 and \$1.13:€1.00).

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Genetic Diseases

Genetic Diseases product sales for the three and six months ended June 30, 2016 increased 16% and 14%, respectively (up 17% and 16%, respectively, on a Non GAAP CER basis) compared to the same periods in 2015.

The increases were primarily driven by increased demand for our Hereditary Angioedema therapies, CINRYZE and FIRAZYR, which were up 25% and 31%, respectively, in the three months ended June 30, 2016 and 18% and 35%, respectively, in the six months ended June 30, 2016 compared to 2015. Both products benefitted from strong growth in the number of patients on therapy, higher utilization per patient in the three and six months ended June 30, 2016 and the impact of pricing actions taken since the second quarter of 2015.

Neuroscience

Neuroscience product sales for the three and six months ended June 30, 2016 increased 23% and 19%, respectively, compared to the same periods in 2015 with growth primarily driven by VYVANSE.

VYVANSE sales increased 22% in both the three and six months ended June 30, 2016 compared to the same periods in 2015. The increases were due to year-over-year prescription growth in the U.S., the benefit of price increases taken since the second quarter of 2015 and, to a lesser extent, growth in our international markets.

ADDERALL XR sales increased 18% and 10% in the three and six months ended June 30, 2016, respectively, compared to the same periods in 2015. The increases were due to increased prescription demand and lower sales deductions as a percentage of product sales, partially offset in the three months ended June 30, 2016, by destocking versus stocking during the same period of the prior year.

Internal Medicine

Internal Medicine product sales for the three and six months ended June 30, 2016 increased 19% and 18%, respectively, compared to the same periods in 2015, primarily due to continued growth in our gastro-intestinal products.

LIALDA/MEZAVANT sales increased 23% and 18% for the three and six months ended June 30, 2016, respectively, compared to the same periods in 2015. The increases were due to the impact of a price increase taken since the second quarter of 2015, increases in prescription demand, resulting in a market share of 39% as of June 30, 2016, and to a lesser extent, the impact of stocking in the three and six months ended June 30, 2016 versus destocking in the same periods in 2015.

GATTEX/REVESTIVE and NATPARA, which were acquired with NPS in the first quarter of 2015, continued to perform well with sales up 19% and 237%, respectively, for the three months ended June 30, 2016 and 84% and 502%, respectively, for the six months ended June 30, 2016 compared to the same periods in 2015. GATTEX/REVESTIVE sales were up due to an increase in the number of patients on therapy, partially offset by destocking in the three and six months ended June 30, 2016. NATPARA was launched in April 2015.

Hematology

The Hematology franchise was acquired with Baxalta in June 2016 and includes sales of recombinant and plasma-derived hemophilia products (primarily factor VIII and factor IX) and inhibitor therapies. One month of reported product sales, totaling \$350 million, is included in total product sales for both the three and six months ended June 30, 2016 and represents 15% and 9% of Shire's reported product sales, respectively.

Immunology

The Immunology franchise was acquired with Baxalta in June 2016 and includes sales of the Group's antibody-replacement immunoglobulin therapies and bio therapeutic therapies. One month of reported product sales, totaling \$190 million, are included in total product sales for both the three and six months ended June 30, 2016 and represents 8% and 5% of Shire's reported product sales, respectively.

Oncology

The Oncology franchise was acquired with Baxalta in June 2016 and represents less than 1% of Shire's reported product sales for both the three and six months ended June 30, 2016.

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Royalties and other revenues

The following table provides an analysis of Shire's income from royalties and other revenues:

	3 Months ended June 30,				6 Months ended June 30,			
	2016	2015	Change %	Non GAAP CER growth %	2016	2015	Change %	Non GAAP CER growth %
(in millions, except percentages)								
SENSIPAR								
Royalties	\$35.6	\$34.8	+2	+2	\$73.5	\$45.2	+63	+63
3TC and ZEFFIX								
Royalties	12.1	10.5	+15	+16	27.1	18.0	+51	+51
FOSRENOL								
Royalties	11.4	10.8	+6	-4	20.6	19.2	+7	+2
ADDERALL XR								
Royalties	5.2	6.6	-21	-21	11.0	15.1	-27	-27
Other Royalties and Revenues	42.7	18.7	+128	+126	56.8	49.1	+16	+15
Total Royalties and Other Revenues	\$107.0	\$81.4	+31	+30	\$189.0	\$146.6	+29	+28

Royalties and Other Revenues increased 31% and 29% in the three and six months ended June 30, 2016, respectively, compared to the same periods in 2015, primarily due to \$21 million of contract manufacturing revenue acquired with Baxalta. Additionally, SENSIPAR royalties increased in the six months ended June 30, 2016 as the 2016 amount represents a full six months of royalties. Shire acquired royalty rights to SENSIPAR as part of its acquisition of NPS, which closed February 21, 2015, and revenue prior to that date was recognized by NPS.

Cost of sales

Cost of sales increased to \$778.1 million for the three months ended June 30, 2016 (34% of product sales), from \$228.0 million in the corresponding period in 2015 (15% of product sales). Cost of sales increased to \$1,026.7 million for the six months ended June 30, 2016 (26% of product sales), from \$455.8 million in the corresponding period in 2015 (16% of product sales). Cost of sales in each period increased primarily due to the impact of higher amortization of inventory fair value step-ups in 2016 following the acquisitions of Baxalta and Dyax, and, to a lesser extent, the impact of lower margin product franchises acquired with Baxalta. Baxalta expenses included in cost of sales total \$478.2 for both the three and six months ended June 30, 2016.

For the three and six months ended June 30, 2016, cost of sales included depreciation of \$22.4 million and \$30.7 million, respectively (2015: \$13.1 million and \$24.8 million, respectively).

R&D

R&D expenditure decreased to \$294.8 million for the three months ended June 30, 2016 (13% of product sales), compared to \$775.9 million in the corresponding period in 2015 (53% of product sales). R&D expenditure decreased to \$511.9 million for the six months ended June 30, 2016 (13% of product sales), compared to \$969.6 million in the corresponding period in 2015 (33% of product sales). These decreases are due to IPR&D impairment charges of \$523 million recorded in the second quarter of 2015 related to the SHP625 and SHP608 intangible assets. Baxalta expenses included in R&D total \$53.9 million for both the three and six months ended June 30, 2016.

For the three and six months ended June 30, 2016, R&D included depreciation of \$5.8 million and \$11.7, respectively (2015: \$8.9 million and \$11.7 million, respectively).

SG&A

SG&A expenditure increased to \$675.3 million for the three months ended June 30, 2016 (29% of product sales), from \$496.0 million in the corresponding period in 2015 (34% of product sales). SG&A expenditure increased to \$1,150.2 million for the six months ended June 30, 2016 (29% of product sales) from \$914.3 million in the corresponding period in 2015 (32% of product sales). These increases are primarily due to the inclusion of Baxalta

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related costs in the 2016 periods. Excluding Baxalta costs of \$144 million in both the three and six months ended June 30, 2016, SG&A increased primarily due to higher marketing spend for XIIDRA launch preparations.

For the three and six months ended June 30, 2016, SG&A included depreciation of \$19.7 million and \$39.8 million, respectively (2015: \$17.9 million and \$35.7 million, respectively).

Reported SG&A for periods prior to the second quarter 2016 have been recast to exclude amortization of acquired intangible assets, which is now presented as a separate account line in the Group's Unaudited Consolidated Statements of Operations.

Reorganization costs

For the three and six months ended June 30, 2016, Shire recorded reorganization costs of \$11.0 million and \$14.3 million, respectively (2015: \$13.3 million and \$28.5 million, respectively), primarily related to the closure of the Basingstoke office and the relocation of roles from Pennsylvania to Massachusetts.

Integration and acquisition costs

For the three and six months ended June 30, 2016, Shire recorded integration and acquisition costs of \$362.8 million and \$453.9 million, respectively, primarily related to the Baxalta and Dyax transactions, slightly offset by changes in the fair value of contingent consideration liabilities.

For the three and six months ended June 30, 2015, Shire recorded a net credit for integration and acquisition costs of \$212.4 million and \$136.7 million, respectively, comprising costs primarily related to the acquisition and integration of NPS of \$45.7 million and \$119.0 million, respectively offset by a net credits of \$258.1 million and \$255.7 million, respectively, relating to the change in fair values of contingent consideration liabilities primarily relating to SHP625 (acquired with Lumena Pharmaceuticals, Inc. ("Lumena")) and SHP608 (acquired with Lotus Tissue Repair, Inc. ("Lotus Tissue Repair")).

Amortization of acquired intangible assets

For the three and six months ended June 30, 2016, Shire recorded amortization of acquire intangible assets of \$213.0 million and \$347.6 million, respectively, compared to \$131.3 million and \$219.6 million, respectively, in the corresponding periods in 2015. The increases relate to amortization on the intangible assets acquired with the Baxalta and Dyax transactions.

Interest expense

For the three and six months ended June 30, 2016, Shire incurred interest expense of \$87.2 million and \$131.9 million, primarily due to increased interest expense and amortization of one-time borrowing costs on borrowings used to fund the Baxalta and Dyax transactions.

For the three and six months ended June 30, 2015, Shire incurred interest expense of \$11.3 million and \$20.9 million, respectively, primarily related to interest and amortization of financing fees incurred on borrowings to fund the NPS acquisition.

Taxation

The effective tax rate on income from continuing operations for the three and six months ended June 30, 2016 was -427% and 2%, respectively (2015: -37% and 2%, respectively).

The effective tax rate for the three and six months ended June 30, 2016 is affected by the combined impact of the relative quantum of the profit before tax for the period by jurisdiction and of the reversal of deferred tax liabilities from the Baxalta acquisition (including in higher tax territories such as the U.S.) of inventory and intangible assets amortization as well as significant acquisition and integration costs.

The effective tax rate for the three months ended June 30, 2015 was negative primarily due to the reduction in deferred tax liabilities in relation to the impairment of IPR&D intangible assets, the re-measurement of uncertain tax positions relating to ongoing tax audits and the release of certain valuation allowances all recognized during the second quarter of 2015.

The Group has historically calculated the provision for income taxes during interim reporting periods by applying an estimate of the annual effective tax rate for the full year to ordinary income or loss for the reporting period. For the three and six months ended June 30, 2016, the impact of certain items arising from the Baxalta acquisition has caused significant variations in the estimated effective tax rate when compared to the three and six months ended June 30, 2015. As a result, the Group has applied a permitted exception to the general rule by including the actual income tax effect of certain portions of its business discretely when calculating the provision for income taxes for the three and six months ended June 30, 2016.

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Discontinued operations

The loss from discontinued operations for the three and six months ended June 30, 2016 was \$248.7 million and \$239.2 million, respectively, net of tax (2015: losses of \$4.5 million and \$7.0 million, respectively, net of tax) primarily related to a proposed legal settlement to resolve the previously disclosed Department of Justice investigation associated with the divested DERMAGRAFT business.

The 2015 losses relate to legal costs associated with the Group's prior sale of the DERMAGRAFT business.

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Financial condition at June 30, 2016 and December 31, 2015

Cash & cash equivalents

Cash and cash equivalents increased by \$557.9 million to \$693.4 million as of June 30, 2016 (December 31, 2015: \$135.5 million), primarily due to cash provided by operating activities of \$980 million, as well as \$583.2 million of cash acquired in the acquisition of Baxalta. These increases are partially offset by the cash used in the acquisition of Baxalta, net of borrowings.

Accounts receivable, net

Accounts receivable, net increased by \$1,211.2 million to \$2,412.4 million as of June 30, 2016 (December 31, 2015: \$1,201.2 million), primarily due to amounts acquired from Baxalta, and an increase in revenue. Days sales outstanding increased to 45 days (December 31, 2015: 42 days).

Inventories

Inventories increased by \$5,163.3 million to \$5,798.7 million as of June 30, 2016 (December 31, 2015: \$635.4 million), primarily due to the inventories acquired as part of the acquisitions of Baxalta and Dyax.

Goodwill

Goodwill increased by \$8,814.6 million to \$12,962.4 million as of June 30, 2016 (December 31, 2015: \$4,147.8 million), principally due to the acquisitions of Baxalta and Dyax.

Other intangible assets, net

Other intangible assets, net increased by \$31,717.0 million to \$40,890.3 million as of June 30, 2016 (December 31, 2015: \$9,173.3 million), principally due to the intangible assets acquired with Baxalta and Dyax.

Other non-current assets

Other non-current assets increased by \$276.5 million to \$309.8 million as of June 30, 2016 (December 31, 2015: \$33.3 million), primarily due to an increase in income tax receivable and other long term assets acquired from Baxalta.

Short term borrowings

Short term borrowings increased by \$1,203.7 million to \$2,715.2 million as of June 30, 2016 (December 31, 2015: \$1,511.5 million), primarily reflecting the utilization of short term debt facilities and the \$2,100.0 million revolving credit facilities agreement (the "RCF") to partially fund the acquisition of Dyax.

Other current liabilities

Other current liabilities increased by \$267.5 million to \$411.5 million as of June 30, 2016 (December 31, 2015: \$144.0 million), primarily due to amounts received in the acquisition of Baxalta, including \$139.0 million in amounts due to Baxter.

Long term borrowings

Long term borrowings increased by \$21,242.2 million to \$21,312.1 million as of June 30, 2016 (December 31, 2015: \$69.9 million), reflecting the utilization of the January 2016 Facilities Agreement and the November 2015 Facilities Agreement to fund the acquisitions of Baxalta and Dyax, respectively.

Non-current deferred tax liabilities

Non-current deferred tax liabilities increased by \$7,847.9 million to \$10,053.8 million at June 30, 2016 (December 31, 2015: \$2,205.9 million) primarily due to the acquisitions of Baxalta and Dyax including establishing deferred tax liabilities for the acquired intangible assets partially offset by acquired deferred tax assets.

Other non-current liabilities

Other non-current liabilities increased by \$1,938.0 million to \$2,736.8 million at June 30, 2016 (December 31, 2015: \$798.8 million) principally due to the recognition of contingent consideration and other contingent payable related to the acquisitions of Dyax and Baxalta.

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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; 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 \$693.4 million of cash and cash equivalents as of June 30, 2016.

Shire has a revolving credit facility of \$2,100 million which matures in 2020, \$905 million of which was utilized as of June 30, 2016. The RCF incorporates a \$250 million U.S. dollar and Euro swingline facility operating as a sub-limit thereof.

In connection with the acquisitions of Baxalta and Dyax, Shire entered into a \$5,600 million term loan facility in November 2015 and an \$18.0 billion bridge loan in January 2016. The details of these facility agreements are presented in Note 13, Borrowings, to these Unaudited Consolidated Financial Statements.

In connection with the acquisition of Baxalta, Shire has assumed senior notes issued by Baxalta totaling \$5.0 billion and has assumed \$335.5 million of capital lease obligations.

In addition, Shire has access to certain short-term uncommitted lines of credit which are available to utilize from time to time to provide short-term cash management flexibility. As of June 30, 2016, these lines of credit were not utilized.

The Group may also engage in financing activities from time to time, including accessing the debt or equity capital markets.

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. Certain loans, including the facility agreements (as explained above), have extension options.

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

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Sources and uses of cash

The following table provides an analysis of the Group's gross and net debt position (excluding restricted cash), as of June 30, 2016 and December 31, 2015:

(in millions)	June 30, 2016	December 31, 2015
Cash and cash equivalents ¹	\$693.4	\$135.5
Long term borrowings	(21,312.1)	(69.9)
Short term borrowings	(2,715.2)	(1,511.5)
Other debt	(343.6)	(13.4)
Total debt	(24,370.9)	(1,594.8)
Net debt ²	\$(23,677.5)	\$(1,459.3)

(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 Group). 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 is a Non-GAAP measure. Net debt represents US GAAP cash and cash equivalents less US GAAP short and long term borrowings and other debt (see above). The Group believes that Net debt 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 ended June 30, 2016 decreased by \$33.5 million, or 3%, to \$980.4 million (2015: \$1,013.9 million), primarily due to higher tax payments in the six months ended June 30, 2016 compared to no net tax payment in the comparable period of 2015, and higher interest payments due to the assumed Baxalta senior notes and utilization of debt facilities to partially fund the acquisition of Dyax. These cash decreases are partially offset by strong cash receipts from higher revenues in the six months ended June 30, 2016.

Net cash used in investing activities was \$17,584.8 million in the six months ended June 30, 2016, principally relating to the cash paid for the acquisitions of Baxalta (\$12,367 million, less cash acquired of \$583 million) and Dyax (\$5,934 million, less cash acquired of \$241 million).

Net cash used in investing activities was \$5,234.1 million in the six months ended June 30, 2015, principally relating to the cash paid for the acquisitions of NPS (\$5,125 million, less cash acquired of \$42 million) and Meritage of \$75 million.

Net cash provided by financing activities was \$17,164.2 million for the six months ended June 30, 2016, principally due to the drawings, net of subsequent repayments, made under the RCF, the January 2016 Facilities Agreement and the November 2015 Facilities Agreement to partially fund the acquisitions of Baxalta and Dyax.

Net cash provided by financing activities was \$1,302.5 million for the six months ended June 30, 2015, principally due to the drawings, net of subsequent repayments, made under the RCF and the January 2015 Facilities Agreement to partially fund the NPS acquisition.

Obligations and commitments

Other than the borrowings incurred to finance the acquisitions of Baxalta and Dyax, as outlined above, and contractual obligations assumed through the acquisition of Baxalta, outlined below, during the six months ended June 30, 2016 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, 2015.

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Contractual Obligations assumed from Baxalta

The following presents contractual obligations, excluding accounts payable and accrued liabilities, assumed from Baxalta as of June 30, 2016:

(in millions)	Total	2016	2017-2018	2019-2020	Thereafter
Debt and capital lease obligations	\$ 5,459.1	\$ 6.7	\$ 789.2	\$ 1,036.1	\$ 3,627.1
Interest on debt and capital lease obligations (a)	2,345.4	84.9	331.1	299.4	1,630.0
Operating leases	381.9	31.1	95.7	74.7	180.4
Other long-term liabilities (b)	606.9	-	136.2	66.3	404.4
Purchase obligations (c)	2,112.2	491.5	908.1	589.2	123.4
Contractual obligations	<u>\$ 10,905.5</u>	<u>\$ 614.2</u>	<u>\$2,260.3</u>	<u>\$ 2,065.7</u>	<u>\$ 5,965.3</u>

(a) Interest payments on capital lease obligations are calculated for future periods using interest rates in effect at the end of June 2016. The projected payments only pertain to obligations assumed from Baxalta that were outstanding at June 30, 2016.

(b) Other long-term liabilities include long-term obligations assumed from Baxalta that are not presented separately within the table above. They include, among other items, the fair value of contingent liabilities assumed with the acquisition of Baxalta.

The Group projected the timing of the future cash payments of its other long-term liabilities based on contractual maturity dates (where applicable) and estimates of the timing of payments (for liabilities with no contractual maturity dates). The actual timing of payments could differ from the estimates.

(c) Purchase obligations include agreements to purchase goods, investments or services (including clinical trials, contract manufacturing and capital equipment), including open purchase orders, that are enforceable and legally binding and that specify all significant terms.

The following items assumed from Baxalta have been excluded from the table above:

- Contingent payments to third parties upon the achievement of development, regulatory and commercial milestones, as well as potential royalty payments, associated with collaboration agreements assumed from Baxalta. Potential future milestone payments associated with the acquired collaborations was approximately \$1.8 billion as of June 30, 2016 which excludes potential royalty payments.
- An unfunded commitment at June 30, 2016 of \$68.4 million as a limited partner in multiple investment companies, in which the timing of future payments is uncertain.
- Long-term liability relating to gross unrecognized tax benefits of \$18.4 million assumed from Baxalta in which the timing of reversal is uncertain.
- Cash outflows related to the assumed pension and other post-employment benefit plans, in which timing of funding is uncertain and dependent on future movements in interest rates and investment returns, changes in laws and regulations and other variables.

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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 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, 2015, which are available on the Group's website, www.shire.com.

Set out below are the principal risks and uncertainties affecting the Group for the remaining six months of 2016 that have been identified through the Group's risk management and internal control systems. The Group believes that these risk factors apply equally and therefore all should be carefully considered before any investment is made in Shire.

Shire's combination with Baxalta closed on June 3, 2016. All references to the "Group," "Shire," "we," "us," or "our" used herein refer to Shire plc and its subsidiaries, including Baxalta and its subsidiaries.

Risks Related to Our Business

The Group's products may not be a commercial success

The commercial success of the Group's marketed products and other new products that the Group may launch in the future, will depend on their approval and acceptance by physicians, patients and other key decision-makers, as well as the receipt of marketing approvals in different countries, the time taken to obtain such approvals, the scope of marketing approvals as reflected in the product labels, approval of reimbursement at commercially sustainable prices in those countries where price and reimbursement is negotiated, and safety, efficacy, convenience and cost-effectiveness of the product as compared to competitive products.

The Group's revenues, financial condition or results of operations may be adversely affected if any or all of the following occur:

- if the Group's products, or competitive products, are genericized;
- if the prices of the Group's products suffer forced reductions or if prices of competitor products are reduced significantly;
- if launches of new products or launch of the Group's products in new markets are not successful;
- if there are unanticipated adverse events experienced with the Group's products or those of a competitor's product not seen in clinical trials that impact physicians' willingness to prescribe the Group's products;
- if issues arise from clinical trials being conducted for post-marketing purposes or for registration in another country which raise questions or concerns about a product;
- if the regulatory agencies in one country act in a way that raises concerns for regulatory agencies or for prescribers or patients in another country;
- if there is a reduction in the use of the Group's products by patients, payers or physicians due to the development of or preferences for alternative technologies or treatments;
- if the Group's products are subject to more stringent government regulation than competitor products;
- if patent protection or other forms of exclusivity are lost or curtailed, or if competitors are able to successfully challenge or circumvent the Group's patents or other forms of exclusivity (see Note 20, Legal and other proceedings, of this Half-yearly Report for details of Shire's current litigation);
- if the sizes of the patient populations for the Group's products are less than expected; or
- if there are lawsuits filed or government investigations initiated against Shire, including but not limited to, product liability claims, consumer law claims, payer or reimbursement litigation and prior sales or marketing practices; or
- If there are adverse developments in investigations or government proceedings.

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If the Group is unable to commercialize its products successfully, there may be a material adverse effect on the Group's revenues, financial condition or results of operations.

Increased pricing pressures and limits on patient access as a result of governmental regulations and market developments may affect the Group's future revenues, financial condition and results of operations

The Group's product revenues are subject to increasing pressures from governmental initiatives to regulate or influence prices and access to customers. Regulations in the United States, the European Union and other jurisdictions mandating price controls or imposing constraints on patients' ability to purchase Shire's products significantly impacts its business, and the Group's financial condition and results of operations could be adversely affected in the future by changes in such regulations, practices or policies.

Regulatory measures that could have a material adverse effect on the Group include the imposition of government-approved drug pricing schedules, the use of drug formularies, prohibitions on direct-to-consumer advertising or drug marketing practices, new regulations or new interpretations of existing or historical regulations relating to governmental drug discount or rebate programs that increase the Group's drug discount or rebate liability, and caps or limits on the level of reimbursement provided to the Group by governmental reimbursement schemes for its products.

These pressures have also resulted in market developments, such as the consolidation of managed care organizations and private health insurers that have increased the relative bargaining power of institutional drug purchasers and enhanced their ability to negotiate discounts and extract other concessions in exchange for purchasing Shire's products.

Such regulatory and market developments create downward pressures on the prices at which the Group can offer its products and on the level of reimbursement its treatments receive from health care providers, private health insurers and other organizations, such as health maintenance organizations and managed care organizations.

Additional factors affecting the Group's ability to obtain and maintain adequate prices and levels of reimbursement for its products include:

- higher levels of controls on the use of the Group's products and/or requirements for further price concessions mandated or negotiated by managed health care organizations or government authorities;
- legislative proposals to reform health care and government insurance programs in many of the Group's markets; and
- price controls, unsuccessful government tenders, or non-reimbursement of new medicines or new indications.

Moreover, the cost of treatment for some of the Group's products is high, particularly those which are used for the treatment of rare diseases. The Group may encounter difficulty in obtaining or maintaining satisfactory pricing and reimbursement for such products. The failure to obtain and maintain pricing and reimbursement at satisfactory levels for its products may adversely affect the Group's revenues, financial condition or results of operations.

The Group depends on third parties to supply certain inputs and services critical to its operations including certain inputs, services and ingredients critical to its manufacturing processes

The Group relies on third-party suppliers, vendors and outsourcing partners to, among other things, research, develop, manufacture and commercialize its products, to provide certain key ingredients and manufacturing inputs and to manage certain sales, distribution, marketing, information technology, accounting, transaction-processing and other business services. While the Group depends on these third parties for multiple aspects of its product development, manufacturing, commercialization and business activities, it does not control these third parties directly.

As a result, there is a possibility these third parties may not complete activities on schedule or in accordance with the Group's expectations, and their failure to meet certain contractual, regulatory or other obligations to Shire, or any disruption of Shire's relationship with these third parties could delay or prevent the development, approval, manufacture or commercialization of the Group's products, result in non-compliance with applicable laws and regulations, disrupt Shire's operations, or result in reputational or other harm to the Group.

This outsourcing risk is of particular concern with respect to third-party suppliers of key manufacturing inputs of Shire's drug products. Although the Group dual-sources certain key products and/or active ingredients, the Group currently relies on a single source for production of the final drug product for each of ADDERALL XR, CINRYZE,

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FIRAZYR, FOSRENOL, INTUNIV, LIALDA, PENTASA and NATPARA/NATPAR. In addition, the Group currently relies on a single active ingredient source for each of ELAPRASE, FIRAZYR, FOSRENOL, INTUNIV, REPLAGAL and GATTEX/REVESTIVE and also relies on limited third party sources to provide the donated plasma necessary for the manufacture of CINRYZE.

As a result of the acquisition of Dyax in January 2016, Shire acquired SHP 643 (formerly DX-2930), which currently relies on separate sole sources for both production of the final drug product and supply of the active ingredient for its Phase 3 trial. In addition, one of those drug substance sites has not been approved by the FDA and would need to be approved prior to commercial launch.

Further, as a result of the combination with Baxalta in June 2016, the Group acquired certain products that include components and materials that are provided by a sole supplier. For most of the components and materials for which a sole supplier is used, the Group believes that alternative sources of supply exist and has made a strategic determination to continue use of a sole supplier. In very limited instances, however, including with respect to a single material used in ADVATE, ADYNOVATE and HYQVIA, the Group relies on sole supplier relationships for which no alternatives have currently been identified. The Group mitigates potential supply disruption by holding strategic inventory and by maintaining insurance for certain risks, but there can be no assurance that such measures will be effective.

Any failure by a single-source supplier to provide the Group with the required volumes on time or at all, or to provide products that do not meet regulatory requirements, could lead to significant delays in the production of Shire's products, increases in operating costs, lost product sales, an interruption of research activities, or the delay of new product launches, all of which could have a material adverse effect on the Group's revenues, financial condition or results of operations.

Any disruption to the supply chain for any of the Group's products, or any difficulties or delays in the manufacturing, distribution and sale of its 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

A disruption, delay or other difficulties in the manufacturing, distribution and sale of Shire's products, or in the supply chain of any of its products, may have a material adverse effect on the Group and its revenues, financial condition and results of operations. Examples of such manufacturing and supply chain difficulties include, but are not limited to:

- regulatory or enforcement actions that result in shut-downs, delays in or withdrawal of regulatory approvals necessary to carry on manufacturing activities, product recalls and penalties or fines resulting in unanticipated costs in production, whether imposed directly on the Group or imposed indirectly through one or more of its third-party suppliers;
- the inability of the Group to increase its production capacity for certain drugs commensurate with market demand;
- the possibility that the supply of incoming materials may be delayed or become unavailable and that the quality of incoming materials may be substandard and not detected;
- the possibility that the Group may fail to maintain appropriate quality standards throughout its internal and third-party supply network, or to comply with current manufacturing best practices, rules or other applicable regulations;
- disruptions to supply chain continuity as a result of natural or man-made disasters at the Group's facilities or at one or more of its third-party suppliers' facilities; and
- failure to maintain the integrity of the Group's supply chains against fraudulent and criminal acts, such as intentional product adulteration, diversion, theft, or counterfeiting activities.

Also, as noted above, the Group has also entered into many agreements with third parties for the provision of goods and services to enable it to manufacture its products. If these third parties are unable to manufacture products, or provide these goods and services, in each case in accordance with its respective contractual obligations, the Group's ability to manage its manufacturing processes or to operate its business, including to continue the development or commercialization of its products as planned or on a commercial basis, may be adversely impacted.

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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

Pharmaceutical and device manufacturing sites must be inspected and approved by regulatory agencies such as the FDA and similar agencies in other countries. Active ingredients, excipients and packaging materials used in the manufacturing process must be obtained from sources approved by regulatory agencies.

The development, approval and manufacturing of the Group's products depend on the ability to procure ingredients and packaging materials from approved sources and for the manufacturing process to be conducted at approved sites. Changes of manufacturer or changes of source of ingredients or packaging materials must generally be approved by the regulatory agencies, which will involve testing and additional inspections to ensure compliance with the applicable regulatory agency's regulations and standards. The need to qualify a new manufacturer or source of ingredients or packaging materials can take a significant amount of time. Should it become necessary to change a manufacturer or supplier of ingredients or packaging materials, or to qualify an additional supplier, the Group may not be able to do so quickly, or at all, which could delay or disrupt the manufacturing process.

U.S.-based manufacturers must be registered with the DEA and similar regulatory authorities in other countries if they handle controlled substances. Certain of the Group's products, including ADDERALL XR and VYVANSE, contain ingredients which are controlled substances subject to quotas managed by the DEA. As a result, the Group's procurement and production quotas may not be sufficient to meet commercial demand.

Certain of the Group's products, including but not limited to CINRYZE, ELAPRASE, REPLAGAL, FEIBA, HYQVIA and GAMMAGARD LIQUID and VPRIV are manufactured using highly complex biological processes. The complexity of the manufacturing results in a number of risks, including the risk of microbial contamination. Additionally, some of the Group's therapies, including CINRYZE, FEIBA, HYQVIA and GAMMAGARD LIQUID are derived from human plasma, and are therefore subject to the risk of biological contamination inherent in plasma-derived products. For example, the sole manufacturer of CINRYZE has received Form FDA 483 Inspectional Observations, the most recent of which was received in May 2016, and a Warning Letter from the FDA in 2013 identifying issues with respect to the manufacturing process for CINRYZE. Shire continues to work with the manufacturer to promptly respond to the observations and implement corrective actions to the satisfaction of the FDA. Any regulatory interventions, in relation to these, or any other issues, if they occur, may delay or disrupt the manufacture of the Group's products.

The failure to obtain regulatory approvals promptly or at all and/or regulatory 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, the delay of new product launches or constraints on manufacturing output, all of which could have a material adverse effect on the Group's revenues, financial condition and results of operations.

The nature of producing plasma-based therapies may prevent Shire from timely responding to market forces and effectively managing its production capacity

The production of plasma-based therapies is a lengthy and complex process, and Shire sources its plasma both internally and externally through suppliers. Efforts to increase the collection of plasma or the production of plasma-based therapies may include the construction and regulatory approval of additional plasma collection facilities and plasma fractionation facilities. In connection with the combination with Baxalta, the Group acquired a yet to be completed state-of-the-art manufacturing facility near Covington, Georgia to support growth of its plasma-based treatments. The Group continues constructing the Covington facility and commercial production at the facility remains scheduled to begin in 2018. The development of such facilities involves a lengthy regulatory process and is highly capital intensive. In addition, access to and transport and use of plasma may be subject to restrictions by governmental agencies both inside and outside the United States. As a result, the Group's ability to match its collection and production of plasma-based therapies to market demand is imprecise and may result in a failure to meet market demand for its plasma-based therapies or, alternatively, an oversupply of inventory. Failure to meet market demand for Shire's plasma-based therapies may result in customers transitioning to available competitive products resulting in a loss of market share or customer confidence. In the event of an oversupply, Shire may be forced to lower the prices it charges for some of its plasma-based therapies, close collection and processing facilities, record asset impairment charges or take other action which could have a material adverse effect on the Group's revenues, financial condition and results of operations.

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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

Products that initially appear promising in research or development may be delayed or fail to reach later stages of development as:

- preclinical or clinical tests may show the product to lack safety or efficacy;
- delays may be caused by slow enrollment in clinical studies; regulatory requirements for clinical trial drug supplies; extended length of time to achieve study endpoints; additional time requirements for data analysis or dossier preparation; time required for discussions with regulatory agencies, including regulatory agency requests for additional preclinical or clinical data; delays at regulatory agencies due to staffing or resource limitations; analysis of or changes to study design; unexpected safety, efficacy, or manufacturing issues; delays may arise from shared control with collaborative partners in the planning and execution of the product development, scaling of the manufacturing process, or getting approval for manufacturing;
- manufacturing issues, pricing or reimbursement issues, or other factors may render the product economically unviable;
- the proprietary rights of others and their competing products and technologies may prevent the product from being developed or commercialized; or
- submission of an application for regulatory approval of any of the Group's product candidates may be subjected to lengthy review and ultimately rejected.

Success in preclinical and early clinical trials does not ensure that late stage clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit, or prevent regulatory approvals. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict. Moreover, once an application is submitted, additional data may be sought by regulators or an application may be rejected. The Group has a range of programs in its product pipeline that are in or entering late stage clinical development, including a New Drug Application submitted to the FDA for SHP606 for the treatment of signs and symptoms of adults with DED and SHP643 (formerly DX-2930) for the treatment of HAE, which is in Phase 3 clinical trials. If the Group's large-scale or late-stage clinical trials for a product are not successful, the Group will not recover its substantial investments in that product.

In addition, even if the products receive regulatory approval, they remain subject to ongoing regulatory requirements, including, for example, obligations to conduct additional clinical trials or other non-clinical testing, changes to the product label (which could impact its marketability and prospects for commercial success), new or revised requirements for manufacturing, written notifications to physicians, or product recalls or withdrawals.

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 conditions or results of operations

A considerable portion of the Group's product sales are made to major pharmaceutical wholesale distributors, as well as to large pharmacies, in both the U.S. and Europe. For the six months ended June 30, 2016, 42% of the Group's product sales were attributable to three customers in the United States: AmerisourceBergen Drug Corp, McKesson Corp. and Cardinal Health, Inc. In the event of financial failure of any of these customers there could be a material adverse effect on the Group's revenues, financial condition or results of operations. The Group's revenues, financial condition or results of operations may also be affected by fluctuations in customer buying or distribution patterns. These fluctuations may result from seasonality, pricing, wholesaler inventory objectives, or other factors. A significant portion of the Group's revenues for certain products for treatment of rare diseases are concentrated within a small number of customers. Changes in the buying patterns of those customers may have an adverse effect on the Group's revenues, financial condition or results of operations.

Failure to comply with laws and regulations governing the sales and marketing of its products could materially impact Shire's revenues and profitability

The Group engages in various marketing, promotional and educational activities pertaining to, as well as the sale of, pharmaceutical products and medical devices in a number of jurisdictions around the world. The promotion, marketing and sale of pharmaceutical products and medical devices is highly regulated and the sales and marketing

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practices of market participants, such as the Group, have been subject to increasing supervision by governmental authorities, and Shire believes that this trend will continue.

In the United States, the Group's sales and marketing activities are monitored by a number of regulatory authorities and law enforcement agencies, including the U.S. Department of HHS, the FDA, the U.S. Department of Justice, the SEC and the DEA. These authorities and agencies and their equivalents in countries outside the United States have broad authority to investigate market participants for potential violations of laws relating to the sale, marketing and promotion of pharmaceutical products and medical devices, including the False Claims Act, the Anti-Kickback Statute, the UK Bribery Act of 2010 and the Foreign Corrupt Practices Act, among others, for alleged improper conduct, including corrupt payments to government officials, improper payments to medical professionals, off-label marketing of pharmaceutical products and medical devices, and the submission of false claims for reimbursement by the federal government. Healthcare companies may also be subject to enforcement actions or prosecution for such improper conduct. Any inquiries or investigations into the operations of, or enforcement or other regulatory action against, the Group by such authorities could result in significant defense costs, fines, penalties and injunctive or administrative remedies, distract management to the detriment of the business, result in the exclusion of certain products, or the Group, from government reimbursement programs or subject the Group to regulatory controls or government monitoring of its activities in the future. The Group is also subject to certain ongoing investigations by governmental agencies. For further information, see Note 20, Legal and other proceedings, of this Half-yearly Report.

The Group's products and product candidates face substantial competition in the product markets in which it operates

Shire faces substantial competition throughout its business from international and domestic biopharmaceutical companies of all sizes. Competition is primarily focused on cost-effectiveness, price, service, product effectiveness and quality, patient convenience and technological innovation.

Competition may increase further as existing competitors enhance their offerings or additional companies enter Shire's markets or modify their existing products to compete directly with Shire's products. If Shire's competitors respond more quickly to new or emerging technologies and changes in customer requirements, the Group's products may be rendered obsolete or non-competitive. If Shire's competitors develop more effective or affordable products, or achieve earlier patent protection or product commercialization than the Group does, its operations will likely be negatively affected. If Shire is forced to reduce its prices due to increased competition, Shire's business could become less profitable. The Group's sales could be adversely affected if any of its contracts with customers (including with hospitals, treatment centers and other health care providers, distributors, group purchasing organizations and integrated delivery networks) are terminated due to increased competition or otherwise.

The Group's patented products are subject to significant competition from generics

In addition to the competition referred to above, Shire faces significant competition from the manufacturers of generic drug products in all of its major markets and in the future may face competition with respect to its biologic and biosimilar products. The introduction of lower-priced generics by the Group's competitors or their successful efforts in aggressively commercializing and marketing their alternative drug products pose significant challenges to maintaining Shire's market share, revenues and sales growth.

For example, since 2009, generic versions of ADDERALL XR have been marketed and, since 2014, generic versions of INTUNIV have been marketed in the United States. As a result, product sales of ADDERALL XR and INTUNIV have declined.

Factors which could cause further or more rapid declines in Shire's product sales include:

- the loss or earlier than expected expiration of intellectual property rights or regulatory exclusivity periods with respect to the Group's branded products;
- generic or authorized generic versions of these products capturing more of Shire's branded market share than expected;
- lower prices and the actual or perceived greater effectiveness or safety of generic drug products relative to Shire's branded products;
- the FDA approving additional ANDAs for these products or additional ANDAs for generic versions of these products which, if launched, would further reduce branded market share or impact the amount of Shire's authorized generic product sales;

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- changes in reimbursement policies of third-party payers; or
- changes to the level of sales deductions for branded Shire products for private or public payers.

Should any of the above developments occur, the resulting generic competition could reduce sales and market share of Shire's branded products and have a material adverse effect on the Group's revenues, financial condition or results of operations.

Adverse outcomes in legal matters and other disputes, including the Group'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

During the ordinary course of its business the Group may be involved in claims, disputes and litigation with third parties, employees, regulatory agencies, governmental authorities and other parties. The range of matters of a legal nature that might arise is extremely broad but could include, without limitation, intellectual property claims and disputes, product liability claims and disputes, regulatory litigation, contract claims and disputes, employment claims and disputes, and tax or other governmental agency audits and disputes.

Any unfavorable outcome in such matters could adversely impact the Group's ability to develop or commercialize its products, adversely affect the product sales and profitability of existing products, subject the Group to significant defense costs, fines, penalties, audit findings and injunctive or administrative remedies, distract management to the detriment of the business, result in the exclusion of certain products, or the Group, from government reimbursement programs or subject the Group to regulatory controls or government monitoring of its activities in the future. Any such outcomes could have a material adverse effect on the Group's revenue, financial condition or results of operations. For further information see Note 20, Legal and other proceedings, of this Half-yearly Report.

The Group may fail to obtain, maintain, enforce or defend the intellectual property rights required to conduct its business

The Group's success depends upon its ability and the ability of its partners and licensors to protect their intellectual property rights. Where possible, the Group's strategy is to register intellectual property rights, such as patents and trademarks. The Group also relies on various trade secrets, unpatented know-how and technological innovations and contractual arrangements with third parties to maintain its competitive position. The failure to obtain, maintain, enforce or defend such intellectual property rights, for any reason, could allow third parties to make competing products or impact the Group's ability to develop, manufacture and market its own products on a commercially viable basis, or at all, which could have a material adverse effect on the Group's revenues, financial condition or results of operations.

The Group intends to enforce its patent rights vigorously and believes that its commercial partners, licensors and third party manufacturers intend to enforce vigorously those patent rights they have licensed to the Group. However, the Group's patent rights, and patent rights that the Group has licensed, may not provide valid patent protection sufficiently broad to prevent any third party from developing, using or commercializing products that are similar or functionally equivalent to the Group's products or technologies. These patent rights may be challenged, revoked, invalidated, infringed or circumvented by third parties. Laws relating to such rights may in future also be changed or withdrawn.

Additionally, the Group's products, or the technologies or processes used to formulate or manufacture those products may now, or in the future, infringe the patent rights of third parties. It is also possible that third parties will obtain patent or other proprietary rights that might be necessary or useful for the development, manufacture or sale of the Group's products. The Group may need to obtain licenses for intellectual property rights from others and may not be able to obtain these licenses on commercially reasonable terms, if at all.

The Group also relies on trade secrets and other un-patented proprietary information, which it generally seeks to protect by confidentiality and nondisclosure agreements with its employees, consultants, advisors and partners. These agreements may not effectively prevent disclosure of confidential information and may not provide the Group with an adequate remedy in the event of unauthorized disclosure. In addition, if the Group's employees, scientific consultants or partners develop inventions or processes that may be applicable to the Group's products under development, such inventions and processes will not necessarily become the Group's property, but may remain the property of those persons or their employers.

The Group has filed applications to register various trademarks for use in connection with its products in various countries and also, with respect to certain products, relies on the trademarks of third parties. These trademarks may not afford adequate protection or the Group or the third parties may not have the financial resources to enforce their rights under these trademarks which may enable others to use the trademarks and dilute their value.

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In the regular course of business, the Group is party to litigation or other proceedings relating to intellectual property rights. For details of current intellectual property litigation, see Note 20, Legal and other proceedings, of this Half-yearly Report.

The Group faces intense competition for highly qualified personnel from other companies and organizations

The Group relies on recruiting and retaining highly skilled employees to meet its strategic objectives. The Group faces intense competition for highly qualified personnel and the supply of people with the requisite skills may be limited, generally or geographically. The range of skills required and the geographies in which they are required by the Group may also change over time as Shire's business evolves. If the Group is unable to retain key personnel or attract new personnel with the requisite skills and experience, it could adversely affect the implementation of the Group's strategic objectives and ultimately adversely impact the Group's revenues, financial condition or results of operations. Recent acquisitions by the Group, including without limitation, the Dyax and Baxalta acquisitions, and the terminated acquisition by AbbVie Inc. ("AbbVie") as well as internal reorganizations and transitions of our offices in Pennsylvania and the United Kingdom may increase the Group's difficulty in recruiting and retaining employees.

Failure to successfully execute or attain strategic objectives from the Group's acquisitions and growth strategy may adversely affect the Group's financial condition and results of operations

The Group's business depends to a significant extent on its ability to improve and expand its product pipeline through strategic acquisitions. Such improvements and expansions, however, are subject to the ability of the Group's management to effectively identify appropriate strategic targets and effectuate the contemplated transactions, the availability and relative cost of acquisition opportunities as well as competition from other pharmaceutical companies seeking similar opportunities.

Moreover, even when such transactions are successfully executed, the Group may face subsequent difficulties in integrating the operations, infrastructure and personnel of acquired businesses and may experience unanticipated risks or liabilities that were not discovered, accurately disclosed or sufficiently assessed during the transactions' due diligence process. Finally, even successfully acquired and integrated businesses may ultimately fail or fall short of achieving the Group's strategic objectives for the transaction over the long term.

Any failures in the execution of a transaction, in the integration of an acquired business or in achieving the Group's strategic objectives, including expected synergies, with respect to such transactions could result in slower growth, higher than expected costs, the recording of asset impairment charges and other actions which could adversely affect the Group's business, financial condition and results of operations.

The Group has recently completed a number of strategic acquisitions, including Dyax in January 2016 and Baxalta in June 2016. Furthermore, the Group is currently exploring, and expects to continue to explore, opportunities for additional strategic acquisitions or combinations in the future. Proposed and completed acquisitions, as well as any future acquisitions, each entail various risks, which include but are not limited to:

- a proposed acquisition may not be consummated due to the occurrence of an event, change or other circumstances that gives rise to the termination of the applicable agreement;
- a governmental, regulatory, board, shareholder or other approval required for a proposed acquisition may not be obtained, or may be obtained subject to conditions that are not anticipated, or another condition to the closing of a proposed acquisition may not be satisfied, resulting in delays or ultimate failure of consummating a proposed acquisition;
- shareholders may initiate legal action to prevent or delay consummation of a proposed acquisition or to seek judicial reevaluation of a proposed acquisition's consideration;
- a lengthy, uncertain process when pursuing a combination could disrupt relationships between Shire and a target Group's customers, suppliers and employees, distract Shire's or a target's management from operating its business, and could lead to additional and unanticipated costs;
- a target Group may be unable to retain and hire key personnel and/or maintain its relationships with customers, suppliers and other business partners pending the consummation of the proposed acquisition by Shire;
- after the consummation of an acquisition, the Group may be unable to retain the acquired Group's key personnel, existing customers, suppliers and other business partners or attract new customers;

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- the businesses of an acquired Group may be otherwise disrupted by the acquisition, including increased costs and diversion of its respective management's time and resources;
- failure to achieve the targeted growth and expected benefits of the acquisition if sales of an acquired Group's products are lower than anticipated, or these products cannot be successfully commercialized or cannot obtain necessary regulatory approvals;
- any integration of an acquired Group into Shire could be complex and time-consuming, and difficulties in effectuating these integrations may lead to the combined companies not being able to realize the expected operating efficiencies, cost savings, revenue enhancements, synergies or other benefits in the timeframe anticipated, or at all;
- failure to successfully obtain regulatory approval of an acquired Group's late stage pipeline assets in a timely manner or at all, or to successfully commercialize such products after regulatory approval has been obtained;
- undiscovered or unanticipated risks and liabilities, including legal and compliance related liabilities, may emerge in connection with an acquisition, or may be higher than anticipated; and
- even after successfully completing an acquisition and integrating the acquired Group's businesses into Shire, the anticipated benefits of the combinations, including expected synergies, may ultimately prove less than anticipated.

Shire's growth strategy depends in part upon its ability to expand its product portfolio through external collaborations, which, if unsuccessful, may adversely affect the development and sale of its products

Shire intends to continue to explore opportunities to enter into collaboration agreements and external alliances with other parties. These third party collaborators may include other biopharmaceutical companies, academic and research institutions, governments and government agencies and other public and private research organizations.

These third party collaborators are often directly responsible for clinical development under these types of arrangements, and the Group does not have the same level of decision-making capabilities for the prioritization and management of development-related activities as it does for its internal research and development activities. Failures by these partners to meet their contractual, regulatory, or other obligations to the Group, or any disruption in the relationships between the Group and these partners, could have a material adverse effect on the Group's pipeline and business. In addition, the Group's collaborative relationships for research and development extend for many years and may give rise to disputes regarding the relative rights, obligations and revenues of Shire and its partners, including the ownership of intellectual property and associated rights and obligations. These could result in the loss of intellectual property rights or other intellectual property protections, delay the development and sale of potential pharmaceutical products, and lead to lengthy and expensive litigation or arbitration.

Long-term public-private partnerships with governments and government agencies, including in certain emerging markets, may include technology transfers to support local manufacturing capacity and technical expertise. Shire cannot predict whether these types of transfers and arrangements will become more common in the future. These types of technology transfers and similar arrangements could have a material adverse effect on the Group's results of operations as a result of lost exclusivity with respect to certain manufacturing and technical capabilities, particularly if this model becomes widely used. Public-private partnerships are also subject to risks of doing business with governments and government agencies, including risks related to sovereign immunity, shifts in the political environment, changing economic and legal conditions and social dynamics.

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

Growth of the global pharmaceutical market has become increasingly tied to global economic growth. Accordingly, a substantial and lasting slowdown of the global economy, or major national economies, could negatively affect growth in the markets in which the Group operates. Such a slowdown, or any resultant austerity measures adopted by governments in response to a slowdown, could result in national governments making significant cuts to their public spending, including national healthcare budgets, or reducing the level of reimbursement they are willing and able to provide to the Group for its products and, as a result, adversely affect the Group's revenues, financial condition or results of operations.

A slowdown of a nation's economy could also lead to financial difficulties for some of the Group's significant customers, including national governments, and result in a greater risk of delayed orders or payments, defaults or

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non-payments of outstanding payment obligations by the Group's customers in that country, which could adversely affect the Group's revenues, financial condition or results of operations.

Changes in foreign currency exchange rates and interest rates could have a material adverse effect on Shire's operating results and liquidity

Shire reports its financial results in U.S. dollars, but generates a substantial portion of its revenue (approximately 28.6% of its total revenue on a pro forma basis in 2016) outside the United States. As a result, Shire's financial results may be adversely affected by fluctuations in foreign currency exchange rates. Shire cannot predict with any certainty changes in foreign currency exchange rates or the ability of the Group to mitigate these risks. Shire may experience additional volatility as a result of inflationary pressures and other macroeconomic factors in certain emerging market countries. Shire is also exposed to changes in interest rates, and Shire's ability to access the money markets and capital markets could be impeded if adverse liquidity market conditions occur.

For discussion of the financial impact of foreign exchange rate and interest rate fluctuations, and the ways and extent to which Shire attempts to mitigate such impact, see Note 12, Financial Instruments, to this Half-yearly Report.

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 Group is subject to evolving and complex tax laws in the jurisdictions in which it operates, and routinely obtains advice on matters, including the tax treatment of the break fee received in connection with the terminated offer for Shire by AbbVie Inc. ("AbbVie") in 2014. Significant judgment is required in determining the Group's tax liabilities, and the Group's tax returns are periodically examined by various tax authorities. The Group regularly assesses the likelihood of outcomes resulting from these examinations to determine the adequacy of its accrual for tax contingencies; however, due to the complexity of tax matters, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. In addition, the Group may be affected by changes in tax laws, including tax rate changes, new tax laws, and revised tax law interpretations in domestic and foreign jurisdictions and between jurisdictions.

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

Unanticipated side effects or unfavorable publicity from complaints concerning any of the Group's products, or those of its competitors, could have an adverse effect on the Group's ability to obtain or maintain regulatory approvals or successfully market its products. The testing, manufacturing, marketing and sales of pharmaceutical products and medical devices entail a risk of product liability claims, product recalls, litigation and associated adverse publicity. The cost of defending against such claims is expensive even when the claims are not merited. A successful product liability claim against the Group could require the Group to pay a substantial monetary award. If, in the absence of adequate insurance coverage, the Group does not have sufficient financial resources to satisfy a liability resulting from such a claim or to fund the legal defense of such a claim, it could become insolvent. Product liability insurance coverage is expensive, difficult to obtain and may not be available in the future on acceptable terms. Moreover, an adverse judgment in a product liability suit could generate substantial negative publicity about the Group's products and business and inhibit or prevent commercialization of other products.

Although biosimilars represent a new opportunity for the Group, the market has an uncertain regulatory framework, and Shire and its partners may not be able to successfully develop and introduce biosimilar products

The Group is working to develop and commercialize biosimilar products, including with its partners. Uncertainty remains concerning both the regulatory pathway in the United States and in other countries to obtain approval of biosimilar products and the commercial pathway to successfully market and sell such products. The Biologics Price Competition and Innovation Act, or the BPCIA, which was passed on March 23, 2010 as Title VII to the PPACA, authorizes the FDA to approve biosimilars through a more abbreviated pathway as compared to new biologics. Although the FDA approved the first biosimilar drug in the United States in March 2015 and recently approved a second biosimilar drug in April 2016, the approval pathway for biosimilar applications remains relatively untested and is subject to ongoing guidance from the FDA. Delays and uncertainties in these approval pathways may result in delays or difficulties in the approval of Shire's biosimilar products by regulatory authorities, subject the Group to unanticipated development costs or otherwise reduce the value of the investments the Group has made in biosimilars. Any such delays, difficulties or unanticipated costs could impact the profitability of Shire's biosimilar products.

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Even if Shire and its partners are able to obtain approvals from the FDA or other relevant regulatory authorities, Shire's biosimilar products and partnerships may not be commercially successful and may not generate profits in amounts that are sufficient to offset the amount invested to develop such biosimilars and obtain such approvals. Biosimilar products could be subject to extensive patent clearances and patent infringement litigation, which could delay or prevent the commercial launch of a product for many years. Market success of biosimilar products will depend on demonstrating to patients, physicians and payors (such as insurance companies) that such products are safe and effective compared to other existing products and offer a more competitive price or other benefit over existing therapies. If Shire's competitors develop biosimilar products more quickly or more efficiently than Shire does, Shire may not be able to effectively execute on its biosimilar strategy. Depending on the outcome of these risks, Shire's sales of biosimilar products and related profitability may not meet Shire's expectations, and Shire's results of operations or financial condition could be adversely affected.

The Group is dependent on information technology and its systems and infrastructure face certain risks, including from service disruptions, the loss of sensitive or confidential information, cyber-attacks and other security breaches or data leakages that could have a material adverse effect on the Group's revenues, financial condition or results of operations

The Group relies to a large extent upon sophisticated information technology systems to operate its businesses. In the ordinary course of business, the Group collects, stores and transmits large amounts of confidential information (including, but not limited to, personal information and intellectual property), and it is critical that the Group does so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of the Group's information technology and information security systems, and those of third-party vendors with whom the Group contracts (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by the Group's employees or vendors, or from attacks by malicious third parties.

The Group and its vendors' sophisticated information technology operations are spread across multiple, sometimes inconsistent platforms, which pose difficulties in maintaining data integrity across systems. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in the Group's systems. The Group and its vendors could also be susceptible to third party attacks on their information security systems, which attacks are of ever increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups, "hackers" and others. While the Group has taken steps to protect such information and invested heavily in information technology, there can be no assurance that these efforts will prevent service interruptions or security breaches in its systems, the loss of data or other confidential information due to a lack of redundant backup systems, or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect the Group's business operations or result in the loss, dissemination, or misuse of critical or sensitive information.

A breach of the Group's security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use the Group's proprietary technology or information, and/or adversely affect the Group's business position. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to the Group and could have a material adverse effect on the Group's revenues, financial condition or results of operations.

In addition, legislators and/or regulators in countries in which the Group operates are increasingly adopting or revising privacy, information security and data protection laws, as well as focusing on increased privacy-related enforcement activity, that potentially could have a significant impact on the Group's current and planned privacy, data protection and information security-related practices, its collection, use, sharing, retention and safeguarding of consumer and/or employee information, and some of its current or planned business activities.

Shire faces risks relating to the expected exit of the United Kingdom from the European Union.

On June 23, 2016, the United Kingdom held a remain-or-leave referendum on the United Kingdom's membership within the European Union, the result of which favored the exit of the United Kingdom from the European Union ("Brexit"). A process of negotiation will likely determine the future terms of the United Kingdom's relationship with the European Union, as well as whether the United Kingdom will be able to continue to benefit from the European Union's free trade and similar agreements. The timing of the Brexit and potential impact of Brexit on Shire's market share, sales, profitability and results of operations is unclear. Depending on the terms of Brexit, economic conditions in the United Kingdom, the European Union and global markets may be adversely affected by reduced growth and volatility. The uncertainty before, during and after the period of negotiation is also expected to have a negative

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economic impact and increase volatility in the markets, particularly in the eurozone. Such volatility and negative economic impact could, in turn, adversely affect the Group's revenues, financial condition or results of operations.

Risks Related to the Combination with Baxalta

The Group may not successfully integrate the businesses of Shire and Baxalta

Achieving the anticipated benefits of the combination of Shire and Baxalta will depend in part upon whether the two companies integrate their businesses in an effective and efficient manner. The Group may not be able to accomplish this integration process successfully or realize the expected synergies as planned. The integration of businesses is complex and time-consuming. The difficulties that could be encountered include the following:

- integrating personnel, operations and systems, while maintaining focus on selling and promoting existing and newly acquired or produced products;
- coordinating geographically dispersed organizations;
- distraction of management and employees from operations;
- changes or conflicts in corporate culture;
- management's inability to manage a substantial increase in the number of employees;
- management's inability to train and integrate personnel, who may have limited experience with the respective companies' business lines and products, and to deliver a consistent message regarding diseases treated by the Group;
- retaining existing customers and attracting new customers;
- retaining existing employees and attracting new employees;
- maintaining business relationships; and
- inefficiencies associated with the integration and management of the operations of the two companies.

In addition, there have been and will continue to be integration costs and non-recurring transaction costs (such as fees paid to legal, financial, accounting and other advisors and other fees paid in connection with the combination) associated with the combination, including costs associated with combining operations and achieving the expected synergies as planned, and such costs may be significant.

An inability to realize the full extent of the anticipated benefits of the combination of Shire and Baxalta, including estimated cost synergies, as well as any delays encountered in the integration process and realizing such benefits, could have an adverse effect upon the revenues, level of expenses and operating results of the Group, which may materially adversely affect the value of the Group's ordinary shares and ADSs.

Shire has incurred significant additional indebtedness in connection with the merger, which has decreased the Group's business flexibility and increased its interest expense. All of the Group's debt obligations, and any future indebtedness the Group may incur, have priority over the Group's ordinary shares and ADSs with respect to payment in the event of a liquidation, dissolution or winding up

The Group has secured an \$18.0 billion fully underwritten bank facility, of which \$12.4 billion was used to finance the cash component of the per share consideration for the combination with Baxalta and the remaining commitment has been cancelled. In connection with the combination, the Group also guaranteed approximately \$5.1 billion of outstanding senior notes issued by Baxalta. The Group also has various financing arrangements, including revolving credit facilities. The Group has announced that it intends to maintain an investment grade credit rating, but one or more credit rating agencies may determine that the Group's, or a subsidiary of the Group's, credit rating is below investment grade due to the merger, which could increase the Group's borrowing costs. The Group's aggregate indebtedness could have the effect, among other things, of reducing the Group's flexibility to respond to changing business and economic conditions as well as reducing funds available for capital expenditures, acquisitions, and creating competitive disadvantages for the Group relative to other companies with lower indebtedness levels. The Group also incurred various costs and expenses associated with the debt financing.

The Group intends to refinance the bank facility through capital market debt issuances in due course. Its ability to refinance the indebtedness will depend on the condition of the capital markets and the Group's financial condition at

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such time. Any refinancing of indebtedness could be at higher interest rates and may require the Group to comply with more onerous covenants, which could further restrict business operations and such refinancing may not be available at all.

Moreover, the Group may be required to raise substantial additional financing to fund capital expenditures and acquisitions. The Group's ability to arrange additional financing and the costs of that financing will depend on, among other factors, the Group's financial position and performance, as well as prevailing market conditions and other factors beyond Shire's control.

In any liquidation, dissolution or winding up of Shire, the Group's ordinary shares and ADSs would rank below all debt claims against Shire or any of its subsidiaries. In addition, any convertible or exchangeable securities or other equity securities that Shire may issue in the future may have rights, preferences and privileges more favorable than those of the Group's ordinary shares and ADSs. As a result, holders of the Group's ordinary shares and ADSs will not be entitled to receive any payment or other distribution of assets upon any liquidation or dissolution until after Shire's obligations to its debt holders and holders of equity securities, which rank senior to the Group's ordinary shares and ADSs, have been satisfied.

Uncertainties associated with the combination may cause a loss of employees and may otherwise affect the future business and operations of Shire and the combined Group

Uncertainty about the effect of the combination on employees and customers may have an adverse effect on the Group following the combination. These consequent uncertainties may impair the Group's ability to retain and motivate key personnel and could also cause customers, suppliers, licensees, partners and other business partners to defer entering into contracts with, making other decisions concerning, or seeking to change existing business relationships with the Group. Because the Group depends on the experience and industry knowledge of their executives and other key personnel to execute their business plans, the Group may be unable to meet its strategic objectives.

Baxalta only operated as an independent Group from July 1, 2015 until the consummation of its merger with U.S. on June 3, 2016, and Baxalta's historical financial information is not necessarily representative of the results that Baxalta would have achieved as a separate, publicly traded Group, and may not be a reliable indicator of future results of Baxalta. Moreover, any pro forma financial information published by the Group is not necessarily representative of the results that the Group would have achieved, and may not be a reliable indicator of future results.

Any historical financial information about Baxalta prior to July 1, 2015 refers to Baxalta's business as operated by and integrated with Baxter. Baxalta's historical and pro forma financial information for such periods was derived from the consolidated financial statements and accounting records of Baxter. In addition, certain pro forma financial information for the Group has incorporated Baxalta's historical financial information for such periods. Accordingly, such historical and pro forma financial information of Baxalta or the Group does not necessarily reflect the financial condition, results of operations or cash flows that Baxalta would have achieved as a separate, publicly traded Group during the periods presented, or those that Shire would have achieved had the combination occurred as assumed for the preparation of the pro forma financial information. As a result, the Group's pro forma financial information is not necessarily representative of the results that the Group will achieve after the merger with Baxalta, and may not be a reliable indicator of future results.

Baxter may not satisfy its obligations under various transaction agreements that have been executed as part of the separation or Shire may fail to have necessary systems and services in place when certain of the transaction agreements expire.

In connection with Baxalta's separation from Baxter, the parties entered into various agreements, including a separation and distribution agreement, a transition services agreement, a tax matters agreement, a manufacturing and supply agreement, an employee matters agreement, license agreements and commercial agreements. The separation and distribution agreement, the tax matters agreement and employee matters agreement determined the allocation of assets and liabilities between the companies following the separation for those respective areas and provide for indemnifications related to liabilities and obligations. The transition services agreement sets forth certain services to be performed by each Group for the benefit of the other for a period of time after the separation. Baxalta and now Shire will rely on Baxter to satisfy its performance and payment obligations under these agreements. If Baxter does not satisfy its obligations under these agreements, including its indemnification obligations, Shire could incur operational difficulties or losses as they relate to Baxalta's businesses. If Shire is unable to successfully integrate the Baxalta businesses into Shire's systems and services, or if Shire does not have agreements with other providers of these services once certain transaction agreements expire, Shire may not be able to operate the Baxalta businesses effectively and Shire's profitability may decline.

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The combination with Baxalta could result in significant liability to the Group if the combination causes the spin-off of Baxalta from Baxter or a Later Distribution, as defined below, to be taxable

In connection with the signing of the merger agreement, Baxter, Shire and Baxalta entered into the Letter Agreement, which, among other things, supplements certain aspects of the tax matters agreement referenced above. Under the Letter Agreement, from and after the closing of the merger, Baxalta agreed to indemnify, and the Group agreed to guarantee such indemnity to, Baxter and each of its affiliates and each of their respective officers, directors and employees against certain tax-related losses attributable to, or resulting from, in whole or in part, the merger. If the contribution of property by Baxter in one or more transfers to Baxalta in exchange for shares of Baxalta common stock, cash, and the assumption of certain liabilities, together with the distribution by Baxter on July 1, 2015 of approximately 80.5% of the shares of Baxalta common stock to shareholders of Baxter (the “spin-off”), Baxter’s distribution of cash received from Baxalta to its creditors and/or a Later Distribution, collectively, the “Baxter Transactions”, are determined to be taxable as a result, in whole or in part, of the merger (for example, if the merger is deemed to be part of a plan, or series of related transactions, that includes the Baxter Transactions), Baxter and its shareholders could incur significant tax liabilities. Under the tax matters agreement, and the Letter Agreement, Baxalta and the Group may be required to indemnify Baxter for any such tax liabilities. Baxter’s waiver of the provisions under the tax matters agreement restricting Baxalta’s ability to enter into and consummate the merger will not relieve Baxalta or the Group of its obligation to indemnify Baxter if the merger causes any of the Baxter Transactions to be taxable.

In connection with the signing and closing of the merger agreement, the Group received an opinion from Cravath, Swaine & Moore LLP (“Cravath”), tax counsel to the Group, to the effect that the merger will not cause the Baxter Transactions to fail to qualify as tax-free to Baxter and its shareholders under Sections 355, 361 and 368(a)(1)(D) of the Internal Revenue Code of 1986, as amended.

The tax opinions referred to in the immediately preceding paragraph are based upon various factual representations and assumptions, as well as certain undertakings made by the Shire, Baxter and Baxalta. If any of the factual representations or the assumptions in the tax opinions are untrue or incomplete in any material respect, an undertaking is not complied with or the facts upon which the tax opinions are based are materially different from the facts at the time of the merger, the opinions may not be valid. Moreover, opinions of counsel are not binding on the Internal Revenue Service (the “IRS”). As a result, the conclusions expressed in the tax opinions could be challenged by the IRS. None of Shire, Baxalta or Baxter has requested a ruling from the IRS regarding the impact of the merger on the tax treatment of the Baxter Transactions, since such rulings are not made by the IRS. Further, the tax opinions do not address all tax aspects of the spin-off, a Later Distribution and other related transactions and it is possible the Group may be obligated to indemnify Baxter despite the continuing validity of the tax opinions.

The Group’s indemnification obligations to Baxter and its affiliates, officers, directors and employees under the tax matters agreement and letter agreement are not limited in amount or subject to any cap. If Baxalta or the Group is required to indemnify Baxter and its affiliates and their respective officers, directors and employees under the circumstances set forth in the tax matters agreement, as supplemented by the Letter Agreement, it could have a material adverse effect on the Group.

In this Half-yearly Report, references to the “Later Distributions” includes the following transactions that were undertaken by Baxter prior to the closing of the merger: (i) two debt-for-equity exchanges (and related underwritten offerings) with respect to Baxalta shares, (ii) an offer to exchange Baxter shares for Baxalta shares, and (iii) a contribution of Baxalta shares to Baxter’s U.S. pension fund, which, in each case, were undertaken prior to the earlier of any Baxalta or Group stockholder vote with respect to the merger and that were intended to be part of a plan that includes the spin-off.

In connection with the merger with Baxalta, the separation and the Later Distributions could result in significant liability to the Group due to Baxalta’s spin-off from Baxter

The Baxter Transactions are intended to qualify for tax-free treatment to Baxter and its stockholders under Sections 355, 361, and 368(a)(1)(D) of the Code. Completion of the separation was conditioned upon, among other things, the receipt of a private letter ruling from the IRS regarding certain issues relating to the tax-free treatment of the Baxter Transactions. Although the IRS private letter ruling is generally binding on the IRS, the continuing validity of such ruling is subject to the accuracy of factual representations and assumptions made in the ruling. Completion of the initial distribution of Baxalta shares on July 1, 2015 was also conditioned upon Baxter’s receipt of a tax opinion from KPMG LLP, or KPMG regarding certain aspects of the separation not covered by the IRS private letter ruling. The opinion was based upon various factual representations and assumptions, as well as certain undertakings made by Baxter and Baxalta. If any of the factual representations or assumptions in the IRS private letter ruling or tax opinion are untrue or incomplete in any material respect, an undertaking is not complied with, or the facts upon which the IRS private letter ruling or tax opinion are based are materially different from the actual facts relating to

Half-yearly Report

the Baxter Transactions, the opinion or IRS private letter ruling may not be valid. Moreover, opinions of a tax advisor are not binding on the IRS. As a result, the conclusions expressed in the opinion of a tax advisor could be successfully challenged by the IRS.

If the Baxter Transactions are determined to be taxable, Baxter and its stockholders could incur significant tax liabilities, and under the tax matters agreement and the letter agreement which were assumed by Shire following the merger, the Group may be required to indemnify Baxter for any liabilities incurred by Baxter if the liabilities are caused by any action or inaction undertaken by Baxalta following the separation (including as a result of the merger). For additional detail, see Business overview for the six months to June 30, 2016 – Agreements with Baxter above and “The combination could result in significant liability to the Group if the combination causes the spin-off of Baxalta from Baxter or a Later Distribution, as defined below, to be taxable.”

Certain Baxalta agreements may contain change of control provisions that may have been triggered by the merger that, if acted upon or not waived, could cause the Group to lose the benefit of such agreement and incur liabilities or replacement costs, which could have a material adverse effect on the Group

Prior to and following the merger, Baxalta and its affiliates are each party to various agreements with third parties, including certain license agreements, business development-related agreements, production and distribution related agreements, bonding/financing facilities, contracts for the performance of services material to the operations of Baxalta and/or its affiliates, IT contracts, technology licenses and employment agreements that may contain change of control provisions that may have been triggered upon the closing of the merger. Agreements with change of control provisions typically provide for or permit the termination of the agreement upon the occurrence of a change of control of one of the parties which can be waived by the relevant counterparties. In the event that there is such a contract or arrangement requiring a consent or waiver in relation to the merger for which such consent or waiver was not obtained, the Group could lose the benefit of the underlying agreement and incur liabilities or replacement costs, which could have an adverse effect on the Group.

New regulations issued by the U.S. Department of Treasury may impact the Group following the merger with Baxalta.

On April 4, 2016, the U.S. Department of Treasury issued new regulations applicable to acquisitions of U.S. companies by non-U.S. companies. These regulations, among other things, change the manner in which thresholds contained within the so-called “anti-inversion” rules that govern how the combined Group will be taxed are calculated. These calculations are affected by the merger and could impact any future acquisitions of U.S. companies funded in whole or in part by Shire securities. These calculations are complicated and depend on several factors. Moreover, the U.S. Department of Treasury also introduced proposed “earnings stripping” regulations that may, among other things, cause certain related-party debt instruments issued by a U.S. corporation to be treated as equity, resulting in the loss of deductible interest payments for U.S. federal income tax purposes.

These regulations are newly issued and complex, and as such their application to any particular set of facts is uncertain. Shire believes that the regulations are not likely to affect the expected tax position of the Group following the acquisition of Baxalta, which belief is based on, among other things, facts that may change or judgments that may prove to be incorrect and, if incorrect, could have an adverse impact on the expected tax position of the Group.

Furthermore, the U.S. tax authorities could issue additional guidance as to the application of these regulations or issue new regulations that could have an adverse effect on the expected tax position of the Group.

Half-yearly Report

Directors' responsibility statement

The Directors confirm that the 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, 2015, with the exception of the following changes:

- David Kappler retired from the Board on April 28, 2016; and
- Gail Fosler and Albert Stroucken were appointed as non-executive directors on June 3, 2016.

Details of all current Directors are available on Shire's website at www.shire.com.

On behalf of the Board:

Flemming Ornskov, M.D., M.P.H.
Chief Executive Officer
August 5, 2016

Jeffrey Poulton
Chief Financial Officer
August 5, 2016

SHIRE PLC
CONSOLIDATED BALANCE SHEETS
(unaudited, in millions except per share amounts)

	June 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 693.4	\$ 135.5
Restricted cash	20.0	86.0
Accounts receivable, net	2,412.4	1,201.2
Inventories	5,798.7	635.4
Prepaid expenses and other current assets	733.6	197.4
Total current assets	9,658.1	2,255.5
Non-current assets:		
Investments	174.0	50.8
Property, plant and equipment, net	6,596.3	828.1
Goodwill	12,962.4	4,147.8
Intangible assets, net	40,890.3	9,173.3
Deferred tax asset	129.6	121.0
Other non-current assets	309.8	33.3
Total assets	70,720.5	16,609.8
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	3,728.1	2,050.6
Short-term borrowings	2,715.2	1,511.5
Other current liabilities	411.5	144.0
Total current liabilities	6,854.8	3,706.1
Non-current liabilities:		
Long-term borrowings	21,312.1	69.9
Deferred tax liability	10,053.8	2,205.9
Other non-current liabilities	2,736.8	798.8
Total liabilities	40,957.5	6,780.7
Commitments and contingencies		

SHIRE PLC
CONSOLIDATED BALANCE SHEETS (continued)
(unaudited, in millions except per share amounts)

	June 30, 2016	December 31, 2015
Equity:		
Common stock of 5p par value; 1,000 million shares authorized; and 906.9 million shares issued and outstanding (2015: 1,000 million shares authorized; and 601.1 million shares issued and outstanding)	81.0	58.9
Additional paid-in capital	24,473.2	4,486.3
Treasury stock: 9.1 million shares (2015: 9.7 million shares)	(302.3)	(320.6)
Accumulated other comprehensive loss	(385.8)	(183.8)
Retained earnings	5,896.9	5,788.3
Total equity	29,763.0	9,829.1
Total liabilities and equity	\$ 70,720.5	\$ 16,609.8

The accompanying notes are an integral part of these Unaudited Consolidated Financial Statements.

SHIRE PLC
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in millions except per share amounts)

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

SHIRE PLC
CONSOLIDATED STATEMENTS OF OPERATIONS (continued)
(unaudited, in millions except per share amounts)

	3 Months Ended June 30,		6 Months Ended June 30,	
	2016	2015	2016	2015
(Loss)/earnings per ordinary share - basic				
Earnings from continuing operations	\$0.12	\$0.28	\$0.78	\$0.98
Loss from discontinued operations	(\$0.36)	(\$0.01)	(\$0.38)	(\$0.01)
	<u>(\$0.24)</u>	<u>\$0.27</u>	<u>\$0.40</u>	<u>\$0.97</u>
(Loss)/earnings per ordinary share - diluted				
Earnings from continuing operations	\$0.12	\$0.28	\$0.77	\$0.97
Loss from discontinued operations	(\$0.36)	(\$0.01)	(\$0.37)	(\$0.01)
	<u>(\$0.24)</u>	<u>\$0.27</u>	<u>\$0.40</u>	<u>\$0.96</u>
Cash dividends declared and paid per ordinary share	\$0.22	\$0.19	\$0.22	\$0.19
Weighted average number of ordinary shares:				
Basic	682.8	590.5	637.3	589.8
Diluted	<u>682.8</u>	<u>593.2</u>	<u>640.1</u>	<u>593.0</u>

The accompanying notes are an integral part of these Unaudited Consolidated Financial Statements.

SHIRE PLC
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME/(LOSS)
(unaudited, in millions)

	3 Months Ended June 30,		6 Months Ended June 30,	
	2016	2015	2016	2015
Net (loss)/income	\$(162.1)	\$159.6	\$256.9	\$570.0
Other comprehensive(loss)/income:				
Foreign currency translation adjustments	(220.2)	46.2	(195.5)	(83.3)
Unrealized (loss)/gain on available-for-sale securities (net of tax benefit of \$1.4 for both the three and six months ended June 30, 2016 and \$nil for both the three and six months ended June 30, 2015)	(4.4)	2.6	(4.7)	3.3
Hedging activities, net of tax benefit of \$1.6 for both the three and six months ended June 30, 2016, respectively and \$nil for both the three and six months ended June 30, 2015	(1.8)	-	(1.8)	-
Comprehensive (loss)/income	\$(388.5)	\$208.4	\$54.9	\$490.0

The components of accumulated other comprehensive loss as of June 30, 2016 and December 31, 2015 are as follows:

	June 30, 2016	December 31, 2015
Foreign currency translation adjustments	\$(377.6)	\$(182.1)
Unrealized holding loss on available-for-sale securities, net of taxes	(6.4)	(1.7)
Hedging activities, net of taxes	(1.8)	-
Accumulated other comprehensive loss	\$(385.8)	\$(183.8)

The accompanying notes are an integral part of these Unaudited Consolidated Financial Statements.

SHIRE PLC
CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
(unaudited, in millions)

	Common stock number of shares	Common stock	Additional paid-in capital	Treasury stock	Accumulated other comprehensive loss	Retained earnings	Total equity
As of January 1, 2016	601.1	\$58.9	\$4,486.3	\$(320.6)	\$(183.8)	\$5,788.3	\$9,829.1
Net income	-	-	-	-	-	256.9	256.9
Other comprehensive loss net of tax	-	-	-	-	(202.0)	-	(202.0)
Options exercised	0.6	0.1	10.7	-	-	-	10.8
Share-based compensation	-	-	194.8	-	-	-	194.8
Tax benefit associated with exercise of stock options	-	-	3.8	-	-	-	3.8
Shares released by employee benefit trust to satisfy exercise of stock options	-	-	-	18.3	-	(18.1)	0.2
Shares issued for the acquisition of Baxalta	305.2	22.0	19,777.6	-	-	-	19,799.6
Dividends	-	-	-	-	-	(130.2)	(130.2)
As of June 30, 2016	906.9	\$81.0	\$24,473.2	\$(302.3)	\$(385.8)	\$5,896.9	\$29,763.0

The accompanying notes are an integral part of these Unaudited Consolidated Financial Statements.

SHIRE PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited, in millions)

	6 Months Ended June 30,	
	2016	2015
	<hr/>	<hr/>
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 256.9	\$ 570.0
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	429.8	291.8
Share-based compensation	194.8	44.3
Change in fair value of contingent consideration	(45.0)	(255.7)
Impairment of intangible assets	8.9	523.3
Amortization of inventory fair value step-up	293.5	16.3
Changes in deferred taxes	(329.2)	(79.4)
Other, net	32.5	(0.3)
Changes in operating assets and liabilities		
Increase in accounts receivable	(181.0)	(84.9)
Increase in sales deduction accruals	66.4	37.3
Increase in inventory	(116.4)	(37.4)
Decrease in prepayments and other assets	26.5	28.4
Increase/(decrease) in accounts and notes payable and other liabilities	342.7	(39.8)
	<hr/>	<hr/>
Net cash provided by operating activities	980.4	1,013.9
CASH FLOWS FROM INVESTING ACTIVITIES:		
Movements in restricted cash	67.2	(19.5)
Purchases of businesses, net of cash acquired	(17,476.2)	(5,249.2)
Purchases of non-current investments and PP&E	(179.1)	(44.7)
Proceeds from short-term investments	-	67.0
Proceeds from sale of product rights	5.6	8.8
Proceeds from disposal of non-current investments	-	4.4
Other, net	(2.3)	(0.9)
	<hr/>	<hr/>
Net cash used in investing activities	(17,584.8)	(5,234.1)

SHIRE PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)
(unaudited, in millions)

	6 Months Ended June 30,	
	2016	2015
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from revolving line of credit, long term and short term borrowings	18,895.0	2,925.6
Repayment of revolving line of credit, long term and short term borrowings	(1,500.3)	(1,530.9)
Payment of dividend	(130.2)	(110.2)
Excess tax benefit associated with exercise of stock options	5.1	27.0
Debt issuance costs	(112.3)	(3.7)
Contingent consideration payments	(4.2)	(4.5)
Other, net	11.1	(0.8)
	17,164.2	1,302.5
Effect of foreign exchange rate changes on cash and cash equivalents	(1.9)	(0.7)
	557.9	(2,918.4)
Net increase/(decrease) in cash and cash equivalents	135.5	2,982.4
Cash and cash equivalents at beginning of period	\$ 693.4	\$ 64.0
Cash and cash equivalents at end of period		

Supplemental information associated with continuing operations:

	6 Months Ended June 30,	
	2016	2015
Interest paid	(111.4)	(9.9)
Income taxes (paid)/repaid, net	(253.7)	-

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

Basis of Presentation

These interim financial statements of Shire plc and its subsidiaries (collectively “Shire” or the “Group”) are unaudited. They have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”).

The balance sheet as of December 31, 2015 was derived from audited financial statements but does not include all disclosures required by U.S. GAAP.

These interim Unaudited Consolidated Financial Statements should be read in conjunction with the consolidated financial statements and accompanying notes included in the Group’s Annual Report and Accounts for the year ended December 31, 2015.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from these interim financial statements. However, these interim financial statements include all adjustments, consisting 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.

On June 3, 2016, the Group completed its acquisition of Baxalta Incorporated (“Baxalta”) for \$32.4 billion, representing the preliminary fair value of purchase consideration. The Group’s Unaudited Consolidated Financial Statements include the results of Baxalta from the date of acquisition. For further details regarding the acquisition, please refer to Note 2, Business Combinations of these Unaudited Consolidated Financial Statements.

During the second quarter of 2016, due to the Baxalta acquisition, the Group concluded that it was appropriate to reclassify the Amortization of Acquired Intangibles from the Selling, General and Administrative line item on the Unaudited Consolidated Statements of Operations. Accordingly, the Group reclassified the Amortization of Acquired Intangibles from the Selling, General and Administrative line item in comparative periods to conform to the current classification.

Use of Estimates

The preparation of financial statements, in conformity with U.S. GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenues and expenses, and related disclosure of contingent assets and liabilities. 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, measurement of pension and other post-employment plan obligations and net periodic benefit cost, contingent consideration receivable from product divestments and contingent consideration payable in respect of business combinations and asset purchases and valuation of other assets and liabilities acquired in business combinations. On an on-going basis the Group evaluates its estimates, judgments and methodologies. Actual results may differ from these estimates under different assumptions or conditions.

Accounting Policy Updates

The Group’s significant accounting policies are discussed in Shire’s most recent Annual Report on and Accounts. The following significant accounting policies have been updated as a result of the Baxalta acquisition.

Financial instruments - derivatives

The Group uses derivative financial instruments to manage its exposure to foreign exchange risk to earnings relating to forecasted transactions and recognized assets and liabilities. The Group has assumed derivatives related to the Baxalta acquisition and has elected to apply hedge accounting for certain derivatives.

For each derivative instrument that is designated and effective as a cash flow hedge, the gain or loss on the derivative is recorded in Accumulated Other Comprehensive Income (“AOCI”) and then recognized in earnings consistent with the underlying hedged item. Cash flow hedges are classified in revenues, cost of sales, interest

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expense, and primarily relate to forecasted third-party sales denominated in foreign currencies, forecasted intercompany sales denominated in foreign currencies, and anticipated issuances of debt.

For each derivative instrument that is designated and effective as a fair value hedge, the gain or loss on the derivative is recognized immediately to earnings, and offsets the loss or gain on the underlying hedged item. Fair value hedges are classified in interest income and interest expense, as they hedge the interest rate risk associated with certain of the Group's fixed-rate debt.

The Group uses forward contracts to hedge earnings from the effects of foreign exchange relating to certain of the Group's intercompany and third-party receivables and payables denominated in a foreign currency. These derivative instruments generally are not formally designated as hedges and the terms of these instruments generally do not exceed three months. The fair values of these instruments are included on the balance sheet in current assets / liabilities, with changes in the fair value recognized in the Consolidated Statements of Operations. The cash flows relating to these instruments are presented within net cash provided by operating activities in the consolidated statement of cash flows, unless the derivative instruments are economically hedging specific investing or financing activities.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Group adopts as of the specified effective date. Unless otherwise discussed below, the Group does not believe that the impact of recently issued standards that are not yet effective will have a material impact on the Group's financial position or results of operations upon adoption.

Adopted during the current period

Reporting requirements for development stage entities

In June 2014, the FASB simplified the existing guidance for development stage entities by removing all incremental financial reporting requirements and the exception available for development stage entities when determining whether the development stage entity is a variable interest entity. The elimination of the exception may change the consolidation analysis, consolidation decision, and disclosure requirements for a reporting entity that has an interest in an entity in the development stage. Shire adopted this guidance as of January 1, 2016 with prospective application. The adoption of this guidance did not impact the Group's consolidated financial position, results of operations or cash flows.

Debt Issuance Costs

In April 2015, the FASB issued a new standard that requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. In August 2015, the FASB issued additional guidance which clarified that debt issuance costs related to line-of-credit arrangements can be presented in the balance sheet as an asset and amortized over the term of the line-of-credit arrangement. The recognition and measurement guidance for debt issuance costs were not affected by these amendments.

Shire adopted this guidance as of January 1, 2016 with retroactive application. The Short-term borrowings and Long-term borrowings line items in the Consolidated Balance Sheets and related footnote disclosures for all periods presented have been adjusted. The adoption of this guidance did not impact the Group's results of operations or cash flows.

Cloud Computing Arrangement

In April 2015, the FASB issued guidance to simplify the accounting for fees paid in a cloud computing arrangement. Under the standard, if a cloud computing arrangement includes a software license, then the software license element of the arrangement should be accounted for consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the arrangement should be accounted for as a service contract. Shire adopted this guidance as of January 1, 2016 with prospective application. The adoption of this guidance did not impact the Group's consolidated financial position, results of operations or cash flows.

Measurement-Period Adjustments

In September 2015, the FASB issued guidance to simplify the accounting for adjustments related to business combinations arising within one year of the acquisition. The new standard requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined and record the effect on earnings of those changes as if the accounting had been completed at the acquisition date, and sets forth new disclosure requirements related to the

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adjustments. Shire adopted this guidance as of January 1, 2016 with prospective application. 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 issued new accounting guidance for recognizing revenue from contracts with customers. This new standard supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The new standard also requires additional qualitative and quantitative disclosures.

In August 2015, the FASB issued additional guidance that delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date.

In March 2016, the FASB issued additional guidance on when and how much revenue to recognize when another party (an agent), along with the entity, is involved in providing a good or a service to a customer.

In April 2016, the FASB issued additional guidance on accounting for licenses of intellectual property and identifying performance obligations.

In May 2016, the FASB issued additional guidance on assessing collectability, presentation of sales taxes, noncash consideration, and completed contracts and contract modifications.

In May 2016, the FASB rescinded several SEC Staff Announcements that are codified in ASC 605, including, among other items, guidance relating to accounting for shipping and handling fees and freight services.

The Group is currently evaluating the method of adoption and the potential impact on its financial position and results of operations of adopting this guidance.

Inventory

In July 2015, the FASB issued new guidance which requires an entity to measure inventory at the lower of cost and net realizable value. Net realizable value is defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. This standard is effective for the Group as of January 1, 2017. Early adoption is permitted. The Group is currently evaluating the potential impact on its financial position and results of operations of adopting this guidance.

Financial Instrument Accounting

In January 2016, the FASB issued an update which involves several aspects of the accounting for the recognition and measurement of certain equity investments. This update impacts all non-equity method investments and has consequences on related deferred income tax valuation allowances and certain financial statement related presentation and disclosure requirements. These amendments are effective for the Group as of January 1, 2018. Early adoption is not permitted. The Group is currently evaluating the method of adoption and the potential impact on its financial position and results of operations of adopting this guidance.

Leases

In February 2016, the FASB issued new accounting guidance that will require the recognition of all lease assets and lease liabilities by lessees and sets forth new disclosure requirements for those lease assets and liabilities. The standard requires lessees to recognize right-of-use assets and lease liabilities on the balance sheet using a modified retrospective approach at the beginning of the earliest comparative period in the financial statements. This standard is effective for the Group as of January 1, 2019. Early adoption is permitted. The Group is currently evaluating the potential impact on its financial position and results of operations of adopting this guidance.

Share-Based Payment Accounting

In March 2016, the FASB issued an update which involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. These amendments are effective for the Group as of January 1, 2017. Early adoption is permitted. The Group is currently evaluating the method of adoption and the potential impact on its financial position and results of operations of adopting this guidance.

Going concern

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

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2. Business Combinations

Combination with Baxalta

On June 3, 2016, Shire acquired all of the outstanding common stock of Baxalta for \$18.00 per share in cash and 0.1482 Shire American Depository Shares (“ADSs”) per Baxalta share, or if a former Baxalta shareholder properly elected, 0.4446 Shire ordinary shares per Baxalta share.

Baxalta was a global biopharmaceutical company that focused on developing, manufacturing and commercializing therapies for orphan diseases and underserved conditions in hematology, oncology and immunology.

The preliminary fair value of the purchase price consideration consisted of the following:

(in millions)	Estimated Fair Value	
Cash paid to shareholders	\$	12,366.7
Fair value of stock issued to shareholders		19,353.2
Fair value of partially vested stock options and RSUs assumed		497.6
Contingent consideration payable		166.0
Total Purchase Consideration	\$	32,383.5

The acquisition of Baxalta was accounted for as a business combination using the acquisition method. Shire issued 305.2 million shares to former Baxalta shareholders at the date of the acquisition. For a more detailed description of the fair value of the partially vested stock options and RSUs assumed, please see Note 21, Share based compensation plans, to these Unaudited Consolidated Financial Statements.

The assets acquired and the liabilities assumed from Baxalta have been recorded at their preliminary fair value as of June 3, 2016, the date of acquisition. The Group’s Unaudited Consolidated Financial Statements included the results of Baxalta from the date of acquisition. The amount of Baxalta’s post-acquisition revenues and pre-tax loss included in the Group’s Unaudited Consolidated Statements of Operations for both the three and six months ended June 30, 2016 is \$580.3 million and \$419.8 million respectively. The pre-tax loss in both the three months and six months ended June 30, 2016 includes charges for the unwind of inventory fair value adjustments of \$266.0 million, intangible asset amortization of \$74.1 million and acquisition and integration costs of \$272.9 million.

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The Group's preliminary allocation of the purchase price to the assets acquired and liabilities assumed as of the acquisition date is outlined below.

(in millions)	Preliminary fair value
ASSETS	
Current assets:	
Cash and cash equivalents	\$ 583.2
Accounts receivable, net	1,382.8
Inventories	5,341.1
Other current assets	362.2
Total current assets	<hr/> 7,669.3
Non-current assets:	
Property, plant and equipment, net	5,687.7
Investments	128.2
Goodwill	6,106.4
Other intangible assets, net	
- Currently marketed products	24,550.0
- In-Process Research and Development ("IPR&D")	2,940.0
- Contract based arrangements	72.2
Other non-current assets	103.3
Total assets	<hr/> 47,257.1
LIABILITIES AND EQUITY	
Current liabilities:	
Accounts payable and accrued expenses	1,509.5
Other current liabilities	15.4
Non-current liabilities:	
Assumed indebtedness	5,424.9
Deferred tax liability	6,831.7
Other non-current liabilities	1,092.1
Total liabilities	<hr/> 14,873.6
Preliminary fair value of identifiable assets acquired and liabilities assumed	<hr/> \$32,383.5
Consideration	
Preliminary fair value of purchase consideration	<hr/> \$32,383.5

The Group is currently completing its evaluation of information, assumptions and valuation methodologies it used in its preliminary fair value of the purchase price consideration.

The purchase price allocation is preliminary pending final determination of the fair values of certain assets and liabilities. As of June 30, 2016, certain items related to the fair values of prepaid assets, inventories, intangible assets, property plant and equipment ("PP&E"), deferred rent, deferred revenue, and current and deferred taxes have not been finalized and may be subject to change as additional information is received and certain tax returns are finalized. The finalization of these matters may result in changes to goodwill and these changes may be material. The final determination of these fair values will be completed as soon as possible but no later than one year from the acquisition date.

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Intangible Assets

The fair value of the identifiable intangible assets has been estimated using an income approach, which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the incremental after tax cash flows an asset would generate over its remaining useful life.

Other intangible assets totaling \$24,550.0 million relate to intellectual property (“IP”) rights acquired for Baxalta’s currently marketed products. The estimated useful life of the currently marketed products intangible assets range from 11 to 38 years (weighted average 30 years), with amortization being recorded on a straight line basis.

IPR&D intangible assets totaling \$2,940.0 million represent the value assigned to R&D projects acquired. The IPR&D intangible assets are capitalized and accounted for as indefinite-lived intangible assets and will be subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project and launch of the product, the Group will make a separate determination of the estimated useful life of the IPR&D intangible asset and the related amortization will be recorded as an expense over the estimated useful life.

Some of the more significant assumptions inherent in the development of those asset valuations include the estimated net cash flows for each year for each asset or product (including net revenues, cost of sales, R&D costs, selling and marketing costs, working capital/asset contributory asset charges and other cash flow assumptions), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream, the assessment of each asset’s life cycle, the potential regulatory and commercial success risks, competitive trends impacting the asset and each cash flow stream as well as other factors.

The discount rate used to arrive at the present value at the acquisition date of IPR&D intangible ranged from 10.0% to 11.0% to reflect the internal rate of return and incremental commercial uncertainty in the cash flow projections. No assurances can be given that the underlying assumptions used to prepare the discounted cash flow analysis will not change. For these and other reasons, actual results may vary significantly from estimated results.

Goodwill

Goodwill of \$6,106.4 million, which is not deductible for tax purposes, includes the expected synergies that will result from combining the operations of Baxalta with 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; the value of the assembled workforce; and impacted by establishing a deferred tax liability for the acquired identifiable intangible assets which have no tax basis.

In the three and six months ended June 30, 2016 the Group expensed \$414.5 million and \$442.3 million, respectively, relating to the acquisition and integration of Baxalta, which have been recorded within Integration and acquisition costs in the Group’s Unaudited Consolidated Statements of Operations.

Contingent Consideration

The Group acquired certain contingent obligations classified as contingent consideration related to Baxalta’s historical business combinations. Additional consideration is conditionally due upon the achievement of certain milestones related to the development, regulatory, first commercial sale and other sales milestones, which could total up to approximately \$1.5 billion. The Group may also pay royalties based on certain product sales. The Group estimated the fair value of the contingent consideration acquired to be \$166.0 million using a probability weighting approach that considered the possible outcomes based on assumptions related to the timing and probability of the product launch date, discount rates matched to the timing of first payment, and probability of success rates and discount adjustments on the related cash flows.

Retirement plans

The Group acquired pension plans as part of the acquisition of Baxalta, including defined benefit and post-retirement pension plans in the United States and foreign jurisdictions which had a net liability balance of \$610.4 million. As of June 3, 2016, the Baxalta defined benefit pension plans had assets with a fair value of \$358.5 million.

Supplemental disclosure of pro forma information

The following unaudited pro forma financial information presents the combined results of the operations of Shire and Baxalta as if the acquisitions of Baxalta had occurred as of January 1, 2015. The unaudited pro forma financial information is not necessarily indicative of what the consolidated results of operations actually would have been had the respective acquisitions 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.

(in millions)	3 Months Ended June 30, 2016	2015	6 Months Ended June 30, 2016	2015
Revenues	\$3,484.1	\$2,986.6	\$6,741.4	\$5,836.0
Net income/(loss) from continuing operations	716.0	(401.4)	1,177.3	(976.1)
Per share amounts:				
Net income/(loss) from continuing operations per share - basic	\$ 0.81	\$ (0.45)	\$ 1.33	\$ (1.09)
Net income/(loss) from continuing operations per share - diluted	\$ 0.81	\$ (0.45)	\$ 1.32	\$ (1.09)

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

- (i) an adjustment to increase net income for the three and six months ended June 30, 2016 (by \$361.6 million and \$400.9 million, respectively) to eliminate acquisition related costs incurred by Shire and Baxalta and a corresponding decrease in net income for the six months ended June 30, 2015 by \$400.9 million to give effect to the acquisition of Baxalta as if it had occurred on January 1, 2015;
- (ii) an adjustment to decrease net income for the three and six months ended June 30, 2015 (by \$600.7 million and \$1,201.3 million, respectively) to reflect amortization of the fair value adjustments for inventory as inventory is sold and a corresponding increase in net income by \$206.4 million for both the three and six months ended June 30, 2016;
- (iii) an adjustment to increase amortization expense for the three and six months ended June 30, 2016 (by \$46.8 million and \$201.0 million, respectively) and for the three and six months ended June 30, 2015 (by \$166.7 million and \$333.4 million respectively), related to the identifiable intangible assets acquired;
- (iv) an adjustment for the three and six months ended June 30, 2015 (by \$87.4 million and \$174.0 million, respectively) and for the three and six months ended June 30, 2016 (by \$42.5 million and \$59.0 million respectively) primarily related to the additional interest expense associated with the debt incurred to partially fund the acquisition of Baxalta and the amortization of related deferred debt issuance costs; and
- (v) an adjustment to decrease depreciation expense for the three and six months ended June 30, 2015 (\$5.2 million and \$10.5 million, respectively) and for the three and six months ended June 30, 2016 (\$3.5 million and \$8.7 million respectively) related to the fair value adjustment to property, plant and equipment acquired.

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

Acquisition of Dyax

On January 22, 2016, Shire acquired all of the outstanding common stock of Dyax for \$37.30 per share in cash. Under the terms of the merger agreement, former Dyax shareholders may receive additional value through a non-tradable contingent value right worth \$4.00 per share, payable generally upon U.S. Food and Drug Administration ("FDA") approval of SHP643 (formerly DX-2930) in Hereditary Angioedema ("HAE").

Dyax was a publicly-traded, Massachusetts-based rare disease biopharmaceutical Group primarily focused on the development of plasma kallikrein ("pKal") inhibitors for the treatment of HAE. Dyax's most advanced clinical program was SHP643, a Phase 3 program with the potential for improved efficacy and convenience for HAE patients. SHP643 has received Fast Track, Breakthrough Therapy, and Orphan Drug designations by the FDA and has also received Orphan Drug status in the EU. Dyax's sole marketed product, KALBITOR, is a pKal inhibitor for the treatment of acute attacks of HAE in patients 12 years of age and older.

The acquisition of Dyax was accounted for as a business combination using the acquisition method. The preliminary acquisition-date fair value consideration was \$6,330.0 million, comprising cash paid on closing of \$5,934.0 million and the preliminary fair value of the contingent value right of \$396.0 million (maximum payable \$646.0 million). The

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assets acquired and the liabilities assumed from Dyax have been recorded at their preliminary fair value as of January 22, 2016, the date of acquisition. The Group's Unaudited Consolidated Financial Statements include the results of Dyax as of January 22, 2016.

The amount of Dyax's post-acquisition revenues and pre-tax losses included in the Group's Unaudited Consolidated Statements of Operations for the three months ended June 30, 2016 were \$24.0 million and \$131.9 million, respectively. The pre-tax loss includes charges on the unwind of inventory fair value adjustments of \$1.5 million, intangible assets amortization of \$8.0 million and integration costs of \$9.3 million.

The amount of Dyax's post-acquisition revenues and pre-tax losses included in the Group's Unaudited Consolidated Statements of Operations for the six months ended June 30, 2016 were \$34.6 million and \$186.4 million, respectively. The pre-tax loss includes charges on the unwind of inventory fair value adjustments of \$2.6 million, intangible assets amortization of \$14.0 million and integration costs of \$30.3 million.

In the second quarter of 2016, we adjusted our preliminary valuation and allocation of purchase price consideration. The adjustment, which was not material, decreased goodwill and deferred tax liabilities. The revised preliminary allocation of the total purchase price is as follows:

(in millions)	Fair value
ASSETS	
Current assets:	
Cash and cash equivalents	\$241.2
Accounts receivable, net	13.3
Inventories	20.2
Other current assets	8.1
Total current assets	282.8
Non-current assets:	
Property, plant and equipment, net	5.8
Goodwill	2,727.9
Other intangible assets, net	
- Currently marketed products	135.0
- IPR&D	4,100.0
- Contract based royalty arrangements	425.0
Other non-current assets	28.3
Total assets	7,704.8
LIABILITIES AND EQUITY	
Current liabilities:	
Accounts payable and accrued expenses	30.0
Other current liabilities	1.7
Non-current liabilities:	
Deferred tax liability	1,341.7
Other non-current liabilities	1.4
Total liabilities	1,374.8
Preliminary fair value of identifiable assets acquired and liabilities assumed	\$6,330.0
Consideration	
Preliminary fair value of purchase consideration	\$6,330.0

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The purchase price allocation is preliminary pending final determination of the fair values of certain assets and liabilities. In particular, the fair values of inventories, intangible assets and current and deferred taxes 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.

Currently marketed products

Other intangible assets totaling \$135.0 million relate to intellectual property rights acquired for Dyax's currently marketed product, KALBITOR. The fair value of the currently marketed product has been estimated using an income approach, based on the present value of incremental after tax cash flows attributable to KALBITOR.

The estimated useful life of the KALBITOR intangible asset is 18 years, with amortization being recorded on a straight-line basis.

IPR&D

The IPR&D asset of \$4,100.0 million relates to Dyax's clinical program SHP643, a Phase 3 program with the potential for improved efficacy and convenience for HAE patients. The IPR&D intangible assets are capitalized and accounted for as indefinite-lived intangible assets and will be subject to impairment testing until completion or abandonment of the projects. 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. The estimated cash flows have been probability adjusted to take into account the development stage of completion and the remaining risks and uncertainties surrounding the future development and commercialization.

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.

The estimated probability adjusted after tax cash flows used to estimate the fair value of other intangible assets have been discounted at 9%.

Royalty rights

Other intangible assets totaling \$425.0 million relate to royalty rights arising from licensing agreements of a portfolio of product candidates. This portfolio includes two approved products, marketed by Eli Lilly & Company, and various development-stage products. Multiple product candidates with other pharmaceutical companies are in various stages of clinical development for which the Group is eligible to receive future royalties and/or milestone payments.

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 seven to nine years (weighted average eight years), with amortization being recorded on a straight-line basis.

Goodwill

Goodwill of \$2,727.9 million, which is not deductible for tax purposes, includes the expected synergies that will result from combining the operations of Dyax with 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; the value of the assembled workforce; and impacted by establishing a deferred tax liability for the acquired identifiable intangible assets which have no tax basis.

For the three and six months ended June 30, 2016 the Group expensed \$2.0 million and \$53.7 million, respectively, relating to the acquisition and integration of Dyax, which have been recorded within Integration and acquisition costs in the Group's Unaudited Consolidated Statements of Operations.

Supplemental disclosure of pro forma information

The following unaudited pro forma financial information presents the combined results of the operations of Shire and Dyax as if the acquisition of Dyax had occurred as of January 1, 2015. The unaudited pro forma financial information is not necessarily indicative of what the consolidated results of operations actually would have been had the respective acquisitions 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.

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(in millions)	3 Months Ended June 30,		6 Months Ended June 30,	
	2016	2015	2016	2015
Revenues	\$2,429.1	\$1,584.0	\$4,144.3	\$3,092.8
Net income from continuing operations	88.6	128.3	490.2	406.3
Per share amounts:				
Net income from continuing operations per share - basic	\$ 0.13	\$ 0.22	\$ 0.77	\$ 0.69
Net income from continuing operations per share - diluted	\$ 0.13	\$ 0.22	\$ 0.77	\$ 0.69

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

- (i) an adjustment to increase net income for the three and six months ended June 30, 2016 (by approximately \$2.0 million and \$101.2 million, respectively) to eliminate acquisition related costs incurred by Shire and Dyax and a corresponding decrease in net income for the six months ended June 30, 2015 by approximately \$101.2 million to give effect to the acquisition of Dyax as if it had occurred on January 1, 2015;
- (ii) an adjustment to decrease net income for the three and six months ended June 30, 2015 of \$1.6 million and \$2.3 million, respectively, to reflect amortization of the fair value adjustments for inventory as inventory is sold;
- (iii) an adjustment to increase amortization expense for the three and six months ended June 30, 2015 of \$5.4 million and \$10.8 million, respectively, and \$1.3 million for the six months ended June 30, 2016 related to the identifiable intangible assets acquired; and
- (iv) an adjustment to record interest expense for the three and six months ended June 30, 2015 of \$20.4 million and \$40.8 million, respectively associated with the debt incurred to partially fund the acquisition of Dyax and the amortization of related deferred debt issuance costs.

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

Acquisition of NPS

On February 21, 2015, Shire completed its acquisition of all of the outstanding common stock of NPS. As of the acquisition date, fair value of the cash consideration paid on closing was \$5,220 million.

The acquisition of NPS added GATTEX/REVESTIVE and NATPARA/NATPAR to Shire's portfolio of currently marketed products. GATTEX/REVESTIVE is approved in the U.S. and EU for the treatment of adults with short bowel syndrome ("SBS") who are dependent on parenteral support, a rare and potentially fatal gastrointestinal disorder. NATPARA/NATPAR is approved in the U.S. and indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism ("HPT"), who are not well controlled on calcium and vitamin D alone, a rare endocrine disease.

The acquisition of NPS was accounted for as a business combination using the acquisition method. The assets acquired and the liabilities assumed from NPS have been recorded at their estimated fair values at the date of acquisition, February 21, 2015. The Group's Unaudited Consolidated Financial Statements include the results of NPS from February 21, 2015.

The purchase price allocation for the acquisition of NPS was finalized in the fourth quarter of 2015. The Group's allocation of the purchase price to the estimated fair value of assets acquired and liabilities assumed is outlined below:

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Fair value

(in millions)

ASSETS

Current assets:

Cash and cash equivalents	\$41.6
Short-term investments	67.0
Accounts receivable	33.4
Inventories	89.4
Other current assets	11.1

Total current assets	242.5
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Non-current assets:

Property, plant and equipment, net	4.8
Goodwill	1,551.0
Other intangible assets	
- Currently marketed products	4,640.0
- Royalty rights (categorized as "Other amortized intangible assets")	353.0

Total assets	6,791.3
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LIABILITIES

Current liabilities:

Accounts payable and other current liabilities	75.7
Short-term debt	27.4

Non-current liabilities:

Long-term debt, less current portion	78.9
Deferred tax liabilities	1,385.2
Other non-current liabilities	4.5

Total liabilities	1,571.7
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Fair value of identifiable assets acquired and liabilities assumed	\$ 5,219.6
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Consideration

Cash consideration paid	\$ 5,219.6
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Currently marketed products

Other intangible assets totaling \$4,640.0 million relate to intellectual property rights of NATPARA/NATPAR and GATTEX/REVESTIVE. The estimated fair value of the 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 NATPARA/NATPAR and GATTEX/REVESTIVE intangible assets are 24 years, with amortization being recorded on a straight-line basis.

Royalty rights

Other intangible assets totaling \$353.0 million relate to the royalty rights arising from the collaboration agreements with Amgen Inc ("Amgen"), Janssen Pharmaceutica N.V. ("Janssen") and Kyowa Hakko Kirin Co. Ltd ("Kyowa Hakko Kirin"). Amgen markets cinacalcet HCl as Sensipar in the U.S. and as Mimpara in the EU; Janssen markets tapentadol as Nucynta in the U.S.; and Kyowa Hakko Kirin markets cinacalcet HCl as Regpara in Japan, Hong Kong, Malaysia, Macau, Singapore, and Taiwan. NPS is entitled to royalties from the net sales of these products.

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

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

Goodwill

Goodwill of \$1,551.0 million, which is not deductible for tax purposes, includes the expected synergies that will result from combining the operations of NPS 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; the value of the assembled workforce; and impacted by establishing a deferred tax liability for the acquired identifiable intangible assets which have no tax basis.

Supplemental disclosure of pro forma information

The following unaudited pro forma financial information presents the combined results of the operations of Shire and NPS as if the acquisitions of NPS had occurred as of 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 respective acquisitions 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.

(in millions)	3 Months Ended June 30, 2015	6 Months Ended June 30, 2015
Revenues	\$1,557.6	\$3,075.9
Net income from continuing operations	167.8	526.6
Per share amounts:		
Net income from continuing operations per share - basic	\$0.28	\$0.96
Net income from continuing operations per share - diluted	\$0.28	\$0.95

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

- an adjustment to increase net income for the three and six months ended June 30, 2015 (by approximately \$0.4 million and \$106.8 million, respectively) to eliminate acquisition related costs incurred by Shire and NPS;
- an adjustment to increase net income by \$3.1 million and \$9.2 million for the three and six months ended June 30, 2015 respectively, to reflect charges on the unwind of inventory fair value adjustments as acquisition date inventory is sold;
- an adjustment to increase amortization expense for the three and six months ended June 30, 2015 (by approximately \$nil and \$21.1 million respectively), related to the identifiable intangible assets acquired;

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

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3. Collaborative and other licensing arrangements

The Group is party to certain collaborative or licensing arrangements. 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.

Out-licensing arrangements

The Group has entered into various collaborative and licensing arrangements where it has licensed certain product or intellectual property rights for consideration such as up-front payments, development milestones, sales milestones and/or royalty payments. Under the terms of these collaborative and licensing arrangements, the Group may receive development milestone payments up to an aggregate amount of \$32.0 million and sales milestones up to an aggregate amount of \$42.7 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 ended June 30, 2016, the Group received cash related to up-front and milestone payments of \$0.5 million (2015: \$12.6 million). No amount was received in either of the three months ended June 30, 2016 or 2015. In the three and six months ended June 30, 2016, the Group recognized milestone income of \$1.0 million and \$2.3 million, respectively (2015: \$0.5 million and \$1.0 million, respectively), in other revenues of \$16.2 million and \$31.3 million, respectively (2015: \$14.2 million and \$23.4 million, respectively), in product sales for shipment of product to the relevant licensee.

Collaboration and in-licensing arrangements

The Group acquired various collaborative and in-licensing arrangements through its acquisition of Baxalta. These agreements generally provide for commercialization rights to a product or products being developed by the counterparty, and in exchange often resulted in an upfront payment upon execution of the agreement and an obligation that the Group make future development, regulatory approval or commercial milestone payments as well as royalty payments. The following is a description of the significant collaboration agreements acquired as part of the acquisition of Baxalta. The acquisition-date fair value of these collaboration agreements was included in the IPR&D.

Precision BioSciences

In June 2016, the Group acquired a strategic immuno-oncology collaboration with Precision BioSciences ("Precision"), a private biopharmaceutical company based in the United States, specializing in genome editing technology. The Group acquired the collaboration through the acquisition of Baxalta, which previously entered into the agreement in February 2016. Together, Shire and Precision will develop chimeric antigen receptor ("CAR") T cell therapies for up to six unique targets, with the first program expected to enter clinical studies in late 2017. On a product-by-product basis, following successful completion of early-stage research activities up to Phase 2, Shire will have exclusive option rights to complete late-stage development and worldwide commercialization. Precision is responsible for development costs for each target prior to option exercise. Precision also has the right to participate in the development and commercialization of any licensed products resulting from the collaboration through a 50/50 co-development and co-promotion option in the United States. As of the date the agreement was acquired, June 3, 2016 and as of the balance sheet date, the Group had the potential to make future payments related to option fees and development, regulatory and commercial milestones totaling up to \$1.6 billion, in addition to future royalty payments on worldwide sales.

Symphogen

In June 2016, the Group acquired a research, option and commercial agreement with Symphogen, a private biopharmaceutical company headquartered in Denmark that is developing recombinant antibodies and antibody mixtures. The Group acquired the agreement through the acquisition of Baxalta, which previously entered into the agreement in December 2015. Under the terms of the agreement, the Group has options to obtain exclusive licensing rights for three specified proteins in development for the treatment of immune-oncology diseases as well as three additional proteins that may be selected at a later date. Each option is exercisable for a period of 90 days when each protein is ready for Phase 2 clinical trials. Symphogen is responsible for development costs for each protein until option exercise, at which point Shire would become responsible for development costs.

Each option exercise fee is variable depending on when it is exercised, with a maximum exercise price of up to €20 million for each protein. As of the date the agreement was acquired, June 3, 2016 and as of the balance sheet date, the Group had the potential to make additional future payments of up to approximately €1.2 billion related to

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development, regulatory and commercial milestones achieved after option exercise for all six proteins, in addition to future royalty payments.

Merrimack Pharmaceuticals, Inc.

In June 2016, the Group acquired an exclusive license agreement with Merrimack Pharmaceuticals, Inc. ("Merrimack") relating to the development and commercialization of ONIVYDE (nanoliposomal irinotecan injection), also known as "nal-IRI" or MM-398. The Group acquired the agreement through the acquisition of Baxalta, which previously entered into the agreement in September 2014. The arrangement includes all potential indications for nal-IRI across all markets with the exception of the United States and Taiwan. The first indication being pursued is for the treatment of patients with metastatic pancreatic cancer who were previously treated with gemcitabine-based therapy. As of the date the agreement was acquired, June 3, 2016 and as of the balance sheet date, the Group had the potential to make future payments of up to approximately \$678 million related to the achievement of development, regulatory and commercial milestones, in addition to future royalty payments.

Coherus Biosciences, Inc.

In June 2016, the Group acquired an exclusive license agreement with Coherus Biosciences, Inc. ("Coherus") to develop and commercialize a biosimilar to ENBREL® (etanercept), which is indicated for the treatment of certain autoimmune deficiencies, in Europe, Canada, Brazil and certain other markets. The Group acquired the agreement through the acquisition of Baxalta, which previously entered into the agreement in August 2013. The Group also obtained the right of first refusal to certain other biosimilars in the collaboration. Under the terms of the agreement, Coherus is responsible for the development plan, preparation of regulatory filings, and manufacture of the product, subject to certain cost reimbursement by the Group. The Group can terminate the agreement if certain costs exceed a specific cap. As of the date the agreement was acquired, June 3, 2016 and as of the balance sheet date, the Group had the potential to make future payments of up to \$70 million relating to the achievement of development and regulatory milestones, in addition to future royalty payments.

Momenta Pharmaceuticals, Inc.

In June 2016, the Group acquired an exclusive license agreement with Momenta Pharmaceuticals, Inc. ("Momenta") to develop and commercialize biosimilars, including adalimumab (BAX 2923), a biosimilar product candidate for HUMIRA® (adalimumab), which is indicated for the treatment of patients with autoimmune and inflammatory diseases. The agreement was acquired through the acquisition of Baxalta, which initially entered into the agreement in February 2012. The arrangement includes specified funding by the Group, as well as other responsibilities, relating to development and commercialization activities. As of the date the agreement was acquired, June 3, 2016 and as of the balance sheet date, the Group had the potential to make future royalty and profit-sharing payments.

Other arrangements

SFJ Pharmaceuticals Group

On June 19, 2015, Baxalta entered into an agreement with SFJ Pharmaceuticals IX, L.P., a SFJ Pharmaceuticals Group company ("SFJ") relating to BAX 2923, whereby SFJ will fund up to \$165 million of specified development costs related to the BAX 2923 program (with an option to increase funding by an additional \$35 million), in exchange for payments in the event the product obtains regulatory approval in the United States and Europe. The contingent success payments total approximately 5.5 times the incurred and reimbursed development costs and are payable in annual instalments over an approximate nine-year period following the dates of U.S. and EU regulatory approval, respectively. Additionally, there are certain termination provisions that may trigger payment of the contingent success payments prior to regulatory approval. The Group will issue a promissory note to SFJ for the contingent success payments upon U.S. and EU regulatory approval or termination of the agreement, if applicable.

The preliminary fair value of the assumed contingency has been recorded as a long-term liability at June 3, 2016 and as of the balance sheet date, as part of Group's purchase accounting for the Baxalta acquisition. The fair value of the assumed contingency on the date of acquisition was \$288.6 million, which represents the probability adjusted present value of the Group's contingent obligation of \$451.5 million.

Unfunded Contingent Payments

At June 30, 2016, the Group's unfunded contingent milestone payments associated with all of its collaborative and other licensing arrangements acquired from Baxalta totaled \$1.8 billion. This total includes contingent payments associated with R&D costs funded by collaboration partners through June 30, 2016. This total excludes contingent

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royalty and profit-sharing payments, contingent payment liabilities arising from business combinations, potential milestone payments and option exercise fees associated with certain of the Group's collaboration agreements that become payable only if the Group chooses to exercise one or more of its options and potential contingent payments associated with R&D costs that may be funded by collaboration partners in the future.

4. Integration and Acquisition Costs

For the three and six months ended June 30, 2016 Shire recorded integration and acquisition costs of \$363.0 million and \$454.1 million, respectively, primarily related to the acquisitions and integration of Baxalta and Dyax. The Baxalta integration is estimated to be completed by mid to late 2019.

As part of the Group's activities to integrate Baxalta, it terminated certain employees. As of June 30, 2016, the Group incurred costs relating to employee termination benefits of \$253.1 million including severance and acceleration of stock compensation. The Group expects to incur additional integration related severance expense. As of the current period no cash payments related to this severance have been made.

For the three and six months ended June 30, 2015 Shire recorded a net credit to integration and acquisition costs of \$212.4 million and \$136.7 million, respectively. The net credit principally comprises (i) costs related to the acquisition and integration of NPS (\$47.8 million and \$117.7 million in the three and six months ended June 30, 2015, respectively), offset by (ii) a net credit relating to the change in the fair value of contingent consideration liabilities of \$258.1 million and \$255.7 million in the three and six months ended June 30, 2015, respectively. The net credit relating to the change in fair value of contingent consideration liabilities principally relates to the acquisition of 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, 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.

5. Discontinued Operations

Following the sale 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 Group's Unaudited Consolidated Statements of Operations for all periods presented. For the three and six months ended June 30, 2016, the Group recorded a loss of \$248.7 million (net of tax benefit of \$100.9 million) and \$239.2 million (net of tax benefit of \$95.4 million), respectively, primarily related to a provision for a possible civil settlement. For details of the legal provision see Note 20, Legal and other proceedings, to these Unaudited Consolidated Financial Statements.

For the three and six months ended June 30, 2015, the Group recorded a loss of \$4.5 million (net of tax benefit of \$2.6 million) and \$7.0 million (net of tax benefit of \$4.0 million), respectively, related to costs associated with the sale.

6. Accounts Receivable

Accounts receivable at June 30, 2016 of \$2,412.4 million (December 31, 2015: \$1,201.2 million), are net of reserve for discounts and allowances of \$124.4 million (December 31, 2015: \$55.8 million).

Reserve for discounts and allowances:

(in millions)	2016	2015
As of January 1,	\$55.8	\$48.5
Provision charged to operations	269.6	186.6
Payments/credits related to sales	(201.0)	(181.6)
As of June 30,	\$124.4	\$53.5

As of June 30, 2016 accounts receivable included \$100.0 million (December 31, 2015: \$79.0 million) related to royalty income.

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7. Inventories

At June 30, 2016, inventories include \$4,823.6 million in respect of the fair value of inventories acquired with Baxalta, stated at fair value (being estimated selling price less estimated costs to complete and sell). All other inventories are stated at the lower of cost or market. Inventories comprise:

(in millions)	June 30, 2016	December 31, 2015
Finished goods	\$1,389.2	\$184.9
Work-in-progress	3,409.0	302.0
Raw materials	1,000.5	148.5
	<u>\$5,798.7</u>	<u>\$635.4</u>

8. Property, plant and equipment

(in millions)	June 30, 2016	December 31, 2015
Land	\$356.2	\$96.7
Buildings and leasehold improvements	1,965.8	606.4
Machinery, equipment and other	2,158.3	827.4
Assets under construction	2,963.2	93.7
	<u>7,443.5</u>	<u>1,624.2</u>
Less: Accumulated depreciation	(847.2)	(796.1)
	<u>\$6,596.3</u>	<u>\$828.1</u>

Depreciation expense for the three and six months ended June 30, 2016 was \$47.9 million and \$82.2 million, respectively, and for the three and six months ended June 30, 2015 was \$39.9 million and \$72.2 million, respectively.

9. Intangible Assets

(in millions)	IP rights for marketed products	Other intangible assets	IPR&D Unamortized	Total
June 30, 2016				
Gross acquired intangible assets	\$33,929.5	\$872.2	\$8,371.8	\$43,173.5
Accumulated amortization	(2,142.8)	(140.4)	-	(2,283.2)
Other intangible assets, net	<u>\$31,786.7</u>	<u>\$731.8</u>	<u>\$8,371.8</u>	<u>\$40,890.3</u>
December 31, 2015				
Gross acquired intangible assets	\$9,371.9	\$375.0	\$1,362.0	\$11,108.9
Accumulated amortization	(1,852.1)	(83.5)	-	(1,935.6)
Other intangible assets, net	<u>\$7,519.8</u>	<u>\$291.5</u>	<u>\$1,362.0</u>	<u>\$9,173.3</u>

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Other intangible assets are comprised primarily of royalty rights and other contract rights associated with Baxalta, Dyax and NPS.

The change in the net book value of intangible assets for the six months ended June 30, 2016 and 2015 is shown in the table below:

(in millions)	Intangible Assets	
	2016	2015
As of January 1,	\$9,173.3	\$4,934.4
Acquisitions	32,222.2	5,167.8
Amortization charged	(347.6)	(219.6)
Impairment charges	(8.9)	(523.3)
Foreign currency translation	(148.7)	(48.9)
As of June 30,	\$40,890.3	\$9,310.4

In connection with the acquisition of Baxalta on June 3, 2016, the Group acquired IP rights related to marketed products of \$24,550.0 million, IPR&D assets of \$2,940.0 million and other contract rights of \$72.2 million. For a more detailed description of this acquisition, please see Note 2, Business Combinations, to these Unaudited Consolidated Financial Statements.

In connection with the acquisition of Dyax on January 22, 2016, the Group acquired IP rights related to marketed products of \$135 million, IPR&D assets of \$4,100 million and royalty rights of \$425 million. For a more detailed description of this acquisition, please see Note 2, Business Combinations, to these Unaudited Consolidated Financial Statements.

The Group reviews its amortized intangible assets for impairment whenever events or circumstances suggest that their carrying value may not be recoverable. Unamortized intangible assets are reviewed for impairment annually or whenever events or circumstances suggest that their carrying value may not be recoverable.

The estimated future amortization of acquired intangible assets for the next five years is expected to be as follows:

(in millions)	Anticipated future amortization
2016 (remaining six months)	\$ 706.1
2017	1,411.3
2018	1,404.6
2019	1,325.8
2020	1,321.7
2021	1,315.4

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10. Goodwill

The following table provides a roll-forward of the changes in the goodwill balance:

(in millions)	2016	2015
As of January 1,	\$4,147.8	\$2,474.9
Acquisitions	8,834.3	1,720.6
Foreign currency translation	(19.7)	(22.2)
As of June 30,	\$12,962.4	\$4,173.3

The increase in goodwill during the six months ended June 30, 2016 was related to our acquisitions of Baxalta and Dyax. For a more detailed description of these transactions, please see Note 2, Business Combinations, to these Unaudited Consolidated Financial Statements.

11. Fair Value Measurement

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

As of June 30, 2016 and December 31, 2015, 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).

(in millions)	Fair value			
	Total	Level 1	Level 2	Level 3
At June 30, 2016				
Financial assets:				
Marketable equity securities	\$54.4	\$54.4	\$-	\$-
Marketable debt securities	16.8	3.7	13.1	
Contingent consideration receivable	17.5	-	-	17.5
Derivative instruments	65.3	-	65.3	-
Financial liabilities:				
Derivative instruments	40.7	-	40.7	-
Contingent consideration payable	\$993.8	\$-	\$-	\$993.8
At December 31, 2015				
Financial assets:				
Marketable equity securities	\$17.2	\$17.2	\$-	\$-
Contingent consideration receivable	13.8	-	-	13.8
Derivative contracts	1.9	-	1.9	-
Financial liabilities:				
Derivative contracts	11.5	-	11.5	-
Contingent consideration payable	\$475.9	\$-	\$-	\$475.9

Marketable equity securities are included within Investments in the Unaudited Consolidated Balance Sheets. Contingent consideration receivable is included within Prepaid expenses and Other current assets and Other non-current assets in the Unaudited Consolidated Balance Sheets. Contingent consideration payable is included within

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Other current liabilities and Other non-current liabilities in the Unaudited Consolidated Balance Sheets. For derivative see Note 12, Financial Instruments, to these Unaudited Consolidated Financial Statements.

Certain estimates and judgments were required to develop the fair value amounts. The estimated 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:

- Marketable equity securities – the fair values of marketable equity securities are estimated based on quoted market prices for those investments.
- Marketable debt securities – the fair values of debt securities are obtained from pricing services or broker/dealers who either use quoted prices in an active market or proprietary pricing applications, which include observable market information for like or same securities.
- 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).
- Derivative contracts – the fair values of the swap and forward foreign exchange contracts have been determined using the month-end interest rate and foreign exchange rates, respectively.
- 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 following table provides a roll forward of the fair values of our contingent consideration receivable and payables which include Level 3 measurements:

Contingent consideration receivable

	2016	2015
(in millions)		
Balance at January 1,	\$13.8	\$15.9
Change in fair value included in earnings	2.1	8.6
Other	1.6	(7.8)
Balance at June 30,	<u>\$17.5</u>	<u>\$16.7</u>

Contingent consideration payable

	2016	2015
(in millions)		
Balance at January 1,	\$475.9	\$629.9
Additions	562.5	92.1
Change in fair value included in earnings	(45.0)	(255.7)
Other	0.4	(1.6)
Balance at June 30,	<u>\$993.8</u>	<u>\$464.7</u>

The increase in contingent consideration payable is related to the Group's acquisition of Dyax as well as contingent consideration payable assumed in the acquisition of Baxalta. Other primarily includes foreign currency adjustments.

Of the \$993.8 million of contingent consideration payable as of June 30, 2016, \$49.2 million is recorded within Other current liabilities and \$944.6 million is recorded within Other non-current liabilities in the Group's Unaudited Consolidated Balance Sheets.

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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 as follows:

Financial assets:	Fair Value at the Measurement Date			
At June 30, 2016	Fair value	Valuation technique	Significant unobservable inputs	Range
(in millions, except percentages)				
Contingent consideration receivable	\$17.5	Income approach (probability weighted discounted cash flow)	<ul style="list-style-type: none"> • Probability weightings applied to different sales scenarios • Future forecast consideration receivable based on contractual terms with purchaser • Assumed market participant discount rate 	<ul style="list-style-type: none"> • 10 to 90% • \$0 to \$25 million • 8.4%
<hr/>				
Financial liabilities:	Fair Value at the Measurement Date			
At June 30, 2016	Fair value	Valuation technique	Significant unobservable inputs	Range
(in millions, except percentages)				
Contingent consideration payable	\$993.8	Income approach (probability weighted discounted cash flow)	<ul style="list-style-type: none"> • Cumulative probability of milestones being achieved • Assumed market participant discount rate • Periods in which milestones are expected to be achieved • Forecast quarterly royalties payable on net sales of relevant products 	<ul style="list-style-type: none"> • 1 to 90% • 1.5 to 12.4% • 2016 to 2036 • \$1.4 to \$3.8 million

Contingent consideration payable represents future milestones and royalties the Group may be required to pay in conjunction with various business combinations and license agreements.

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 is specific to the individual contingent consideration receivable or payable.

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Financial assets and liabilities that are not measured at fair value on a recurring basis

The carrying amounts and estimated fair values as at June 30, 2016 and December 31, 2015 of the Group's financial assets and liabilities which are not measured at fair value on a recurring basis are as follows:

(in millions)	June 30, 2016		December 31, 2015	
	Carrying amount	Fair value	Carrying amount	Fair value
Financial liabilities:				
Senior notes	\$5,114.0	\$5,114.0	\$-	\$-
Capital lease obligation	348.9	348.9	13.4	13.4

The estimated fair values of long-term debt were computed by multiplying price by the notional amount of the respective debt instrument. Price is calculated using the stated terms of the respective debt instrument and yield curves commensurate with the Group's credit risk. The discount factors used in the calculations reflect the non-performance risk of the Group. The estimated fair value of capital lease obligations is based on Level 2 inputs.

The carrying amounts of other financial assets and liabilities approximate their estimated fair value due to their short-term nature, such as liquidity and 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.

12. 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.

Market Risk

The Company is subject to certain risks which may affect its results of operations, cash flows and fair values of assets and liabilities, including volatility in foreign currency exchange rates, interest rate movements, pricing pressures worldwide and weak economic conditions in the foreign markets in which it operates. The Company manages the impact of foreign currency exchange rates and interest rates through various financial instruments, including derivative instruments such as foreign currency forward contracts, interest rate lock contracts and interest rate swap contracts. The Company does not enter into financial instruments for trading or speculative purposes. The counter-parties to the contracts Company enter into are major financial institutions and there is no significant concentration of exposure with any one counter-party.

Interest Rate Risk

The Company is exposed to the risk that its earnings and cash flows could be adversely impacted by fluctuations in benchmark interest rates relating to its existing debt obligations or anticipated issuances of debt. The Company's policy is to manage this risk to an acceptable level. For details see Note 12, Financial Instruments, to these Unaudited Consolidated Financial Statements.

The Company 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. As the Company 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. For the six months ended June 30, 2016, the average interest rate received on cash and liquid investments was less than 1% per annum. These cash and liquid investments were primarily invested in U.S. dollar term deposits with banks and money market and liquidity funds or held as cash on account.

The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of June 30, 2016, Shire estimates that such hypothetical

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100 basis point adverse movement would result in a hypothetical increase in net interest costs of approximately \$177 million per year and net reduction in the fair value of interest rate sensitive instruments by \$312 million, to its interest rate sensitive instruments.

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 Company receives royalties). Cash is invested in short-term money market instruments, including money market and liquidity funds and bank term deposits or held on account. 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 Company is exposed to the credit risk of the counterparties with which it enters into bank term deposit arrangements and derivative instruments. The Company 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 Shire's Board of Directors and exposure against these limits is monitored by the Company's corporate treasury function. The counterparties to these derivatives contracts are major international financial institutions.

The Company's revenues from product sales in the U.S. are mainly governed by agreements with major pharmaceutical wholesalers and relationships with other pharmaceutical distributors and retail pharmacy chains. For the six months ended June 30, 2016, there were three customers in the U.S. that accounted for 42% of the Company's product sales. However, such customers typically have significant cash resources and as such the risk from concentration of credit is considered acceptable. The Company 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 Company could have an adverse effect on the Company's financial condition and results of operations.

A substantial portion of the Company's accounts receivable in countries outside of the United States is derived from product sales to government-owned or government-supported healthcare providers. The Company'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 Company operates. As a result, in some countries outside of the U.S., specifically, Argentina, Greece, Italy, Portugal and Spain (collectively the "Relevant Countries") the Company is experiencing delays in the remittance of receivables due from government-owned or government-supported healthcare providers. The Company continues to receive remittances in relation to government-owned or government-supported healthcare providers in the Relevant Countries in the six months ended June 30, 2016, including receipts of \$64.9 million and \$58.3 million in respect of Spanish and Italian receivables, respectively. The Company's exposure to Greece, both in terms of gross accounts receivable and annual revenues, is not material.

To date, the Company has not incurred material losses on accounts receivable in the Relevant Countries, and continues to consider that such accounts receivable are recoverable. The Company 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 Company's financial condition and results of operations.

Foreign Exchange Risk

The Company operates 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 operating currencies of the Company are the U.S. dollar, Pounds Sterling, Swiss Franc, Canadian dollar, Japanese Yen and the Euro. It is the Company'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 Company uses foreign exchange contracts (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 Company has not elected hedge accounting for these transactions. Cash flows from

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derivative instruments are presented within net cash provided by operating activities in the Consolidated Statements of Cash Flows, unless the derivative instruments are economically hedging specific investing or financing activities.

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

Foreign Currency Contracts

Due to the global nature of our operations, portions of the Group's revenues and operating expenses are recorded in currencies other than the U.S. dollar. 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 U.S. dollar, Pounds Sterling, Swiss Franc, Canadian dollar, Japanese Yen and the Euro.

The value of revenues and operating expenses measured in U.S. dollars is therefore subject to changes in foreign currency exchange rates. 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 (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. 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 Unaudited Consolidated Balance Sheet.

Designated Derivative Instruments

In connection with the acquisition of Baxalta the Group has assumed foreign currency forward contracts and elected to apply hedge accounting. These contracts have been designated as cash flow hedges and accordingly, to the extent effective, any unrealized gains or losses on these foreign currency forward contracts are reported in AOCI. Realized gains and losses for the effective portion of such contracts are recognized in revenue or cost of sales when the sale of product in the currency being hedged is recognized. To the extent ineffective, hedge transaction gains and losses are reported in Other income/(expense), net. The amount of ineffectiveness for the three and six months ended June 30, 2016 was immaterial.

At June 30, 2016 the foreign currency forward contracts had a total notional value of \$519.0 million with a maximum duration of 12 months. The Group did not have any forward contracts as of December 31, 2015. The portion of the fair value of these foreign currency forward contracts that was included in AOCI in total equity reflected net losses of \$3.4 million as of June 30, 2016. The Group expects all contracts to be settled over the next 12 months and any amounts in AOCI to be reported as an adjustment to revenue or cost of sales. The Group considers the impact of its and its counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its contractual obligations. As of June 30, 2016, credit risk did not change the fair value of the Group's foreign currency forward contracts.

Undesignated Derivative Instruments

The Group uses forward contracts to hedge earnings from the effects of foreign exchange relating to certain of the Group's intercompany and third-party receivables and payables denominated in a foreign currency. These derivative instruments generally are not formally designated as hedges, the terms of these instruments generally do not exceed three months and the change in fair value of these derivatives are reported in earnings. The notional amount of undesignated derivative instruments was \$668.0 million and \$625.5 million as of June 30, 2016 and 2015, respectively.

The Group also has option contracts assumed from Baxalta that were previously designated as cash flow hedges. The notional amount of these option contracts totaled \$37.6 million as of June 30, 2016. Upon acquisition, the Group did not elect to redesignate these option contracts as cash flow hedges. In addition, the Group also assumed undesignated forward contracts from Baxalta. The notional amount of these undesignated forward contracts totaled \$249.3 million as of June 30, 2016.

Interest Rate Contracts

The Group is exposed to the risk that its earnings and cash flows could be adversely impacted by fluctuations in benchmark interest rates relating to its existing debt obligations or anticipated issuances of debt. The Group's policy is to manage this risk to an acceptable level. The Group is principally exposed to interest rate risk on any borrowings under the Group's various debt facilities and assumed in connection with the acquisition of Baxalta. Interest on each

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of these debt obligations is set at fixed and/or floating rates, to the extent utilized. Shire's exposure under these facilities is to changes in U.S. dollar interest rates. For further details related to interest rates on the Group's various debt facilities, please see Note 13 Borrowings and capital lease obligations, to these Unaudited Consolidated Financial Statements.

Designated Derivative Instruments

In connection with the acquisition of Baxalta the Group assumed interest rate swap contracts on certain borrowing transactions. These interest rate swap contracts were related to the issuance of Baxalta's Senior Notes with an aggregate notional amount of \$1.0 billion, mature in June 2020 and June 2025. Subsequent to the acquisition of Baxalta the Group redesignated these interest rate swap contracts as fair value hedges, based on their contractual terms, economic conditions, historic operating or accounting policies, and other conditions that existed at the acquisition date. The effective portion of the changes in the fair value of interest rate swap contracts are recorded as a component of the Senior Notes with immaterial net impact recorded in income. Any net interest payments made or received on the interest rate swap contracts are recognized as a component of interest expense in the Unaudited Consolidated Statements of Operations. For further details related to Baxalta's Senior Notes, please see Note 13, Borrowings and capital lease obligations, to these Unaudited Consolidated Financial Statements. As of June 30, 2016 the fair value of these contracts was \$55.6 million (2015: \$nil) presented within other non-current assets. For the six months ended June 30, 2016, the Group recognized \$22.1 million (2015: \$nil) of gain related to these contracts, which was recognized as a component of interest expense.

Undesignated Derivative Instruments

During the six months ended June 30, 2016, the Group entered into interest rate swap contracts with a total notional amount of \$5.1 billion related to the November 2015 Facilities Agreement. The Group has not elected hedge accounting for these contracts. As of June 30, 2016 the fair value of these contracts was \$4.6 million (2015: \$nil) which is presented within other current liabilities. For the six months ended June 30, 2016, the Group recognized \$4.6 million (2015: \$nil) loss related to these contracts, which was recognized as a component of interest expense.

The following tables summarize the income statement locations and gains and losses on the Group's designated and undesignated derivative instruments for the six months ended June 30, 2016. There were no designated derivatives for the six months ended June 30, 2015.

As of June 30, 2016, the Group had in total 351 swaps and forward foreign exchange contracts.

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Six months ended June 30,	Gain (loss) recognized in OCI		Income Statement location	Gain (loss) reclassified from AOCI into income	
	2016	2015		2016	2015
	(in millions)			(in millions)	
<u>Designated Derivative Instruments</u>					
Cash flow hedges					
Foreign exchange contracts	\$ (3.4)	\$ -	Cost of sales	\$ -	\$ -
	Location of gain (loss) in Income Statement			Gain (loss) recognized in income	
Six months ended June 30,				2016	2015
				(in millions)	
Fair value hedges					
Interest rate contracts	Interest expense			\$22.1	\$ -
<u>Undesignated Derivative Instruments</u>					
Foreign exchange contracts	Other income/(expense), net			(28.8)	21.3
Interest rate swap contracts	Interest expense			(4.6)	-

As of June 30, 2016, \$2.3 million of deferred, net after-tax losses on derivative instruments included in AOCI are expected to be recognized in earnings during the next 12 months, coinciding with when the hedged items are expected to impact earnings.

The following table presents the classification and estimated fair value of the Group's derivative instruments as of June 30, 2016:

(in millions)	Derivatives in asset positions		Derivatives in liability positions	
	Balance Sheet location	Fair Value	Balance Sheet location	Fair Value
<u>Designated Derivative Instruments</u>				
Foreign exchange contracts	Other current assets	\$1.8	Accrued liabilities	\$9.3
Interest rate contracts	Other non-current assets	55.6		-
		<u>\$57.4</u>		<u>\$9.3</u>
<u>Undesignated Derivative Instruments</u>				
Foreign exchange forward contracts	Prepaid and other current assets	\$7.9	Accrued liabilities	\$26.8
Interest rate swap contracts	Prepaid and other current assets	-	Accrued liabilities	4.6
		<u>\$65.3</u>		<u>\$40.7</u>

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As of June 30, 2016, the potential effect of rights of set-off associated with the Interest rate swap and foreign exchange forward contracts would be an offset to both assets and liabilities of \$11.1 million, resulting in net derivative assets and derivative liabilities of \$54.2 million and \$29.6 million, respectively.

13. Borrowings and Capital Lease Obligations

(in millions)	June 30, 2016	December 31, 2015
Short term borrowings:		
Borrowings under the Revolving Credit Facilities Agreement	\$905.0	\$750.0
Borrowings under the November 2015 Facilities Agreement	1,788.3	-
Borrowings under the January 2015 Facilities Agreement	-	750.0
Other borrowings	16.6	11.5
Capital lease obligations (current portion)	5.3	-
	<u>2,715.2</u>	<u>1,511.5</u>
Long term borrowings:		
Senior notes	5,114.0	-
Borrowings under the January 2016 Facilities Agreement	12,341.6	-
Borrowings under the November 2015 Facilities Agreement	3,792.1	-
Other borrowings	64.4	69.9
Capital lease obligations (long term portion)	343.6	-
	<u>\$24,370.9</u>	<u>\$1,581.4</u>

The future payments on debt maturities and capital lease obligations as of June 30, 2016 are as follows:

(in millions)	
2016 (remaining six months)	\$ 1,010.0
2017	2,231.0
2018	15,574.8
2019	44.2
2020	1,946.7
2021	18.5
Thereafter	<u>3,621.3</u>
Total obligations	24,446.5
Fair value hedges, unamortized bond premium and deferred financing costs	<u>(75.6)</u>
Total debt and capital lease obligations	<u>\$ 24,370.9</u>

For a more detailed description of the financing agreements in place prior to the combination with Baxalta, please see below, as well as Note 16, Borrowings, of the Group's Annual Report and Accounts for the year ended December 31, 2015.

Senior Notes

The Group guaranteed senior notes issued by Baxalta with a total aggregate principal amount of \$5 billion in connection with the closing of the Baxalta acquisition ("Senior Notes"). Below is a summary of the Senior Notes assumed by the Group through the Baxalta acquisition as of June 30, 2016:

(in millions, except for percentage information)	Aggregate Principal	Coupon Rate	Effective interest rate in 2016	Carrying amount at June 30, 2016
		LIBOR plus		
Variable-rate notes due 2018	\$ 375.0	0.78%	1.43%	\$ 370.3
Fixed-rate notes due 2018	375.0	2.000%	2.2%	374.7
Fixed-rate notes due 2020	1,000.0	2.875%	3.0%	1,020.0
Fixed-rate notes due 2022	500.0	3.600%	3.7%	509.1
Fixed-rate notes due 2025	1,750.0	4.000%	4.2%	1,807.6
Fixed-rate notes due 2045	1,000.0	5.250%	5.6%	1,032.3
Total assumed Senior Notes				\$ 5,114.0

The effective interest rates above exclude the effect of any related interest rate swaps. The book values above include any premiums and adjustments related to hedging instruments. For further details related to the interest rate derivative contracts, please see Note 12, Financial Instruments, to these Unaudited Consolidated Financial Statements.

Revolving Credit Facilities Agreement

Baxalta Revolving Credit Facilities – cancelled on closing

The \$1,200.0 million senior revolving credit facility and the €200.0 million Euro-denominated senior revolving credit facility available to Baxalta were cancelled by the Group upon the closing of the combination with Baxalta.

Revolving Credit Facilities Agreement

On December 12, 2014, Shire entered into the \$2,100.0 million RCF with a number of financial institutions. As of June 30, 2016 the Group utilized \$905.0 million of the RCF. The RCF, which terminates on December 12, 2020, may be used for financing the general corporate purposes of Shire. The RCF incorporates a \$250.0 million U.S. dollar and Euro swingline facility operating as a sub-limit thereof.

Term Loan Facilities Agreements

January 2016 Facilities Agreement

On January 11, 2016, Shire entered into an \$18.0 billion bridge facilities agreement (the “January 2016 Facilities Agreement”). The January 2016 Facilities Agreement comprises two credit facilities: (i) a \$13.0 billion term loan facility which, subject to a one year extension option exercisable at Shire's option, matures on January 11, 2017 (“January 2016 Facility A”) and (ii) a \$5.0 billion revolving loan facility which, subject to a one year extension option exercisable at Shire's option, matures on January 11, 2017 (“January 2016 Facility B”).

January 2016 Facility A was utilized to finance the cash consideration payable and certain costs related to the acquisition of Baxalta on June 3, 2016 in the amount of \$12,390.0 million. Due to the available extension option without any restrictions, January 2016 Facility A is classified as a long term borrowing. As of June 30, 2016, the Group reduced the January 2016 Facility A commitment by \$610.0 million.

January 2016 Facility B was cancelled effective July 11, 2016, in accordance with its terms.

November 2015 Facilities Agreement

On November 2, 2015, Shire entered into a \$5.6 billion facilities agreement (the “November 2015 Facilities Agreement”). The November 2015 Facilities Agreement comprises three credit facilities: (i) a \$1.0 billion term loan facility which, subject to a one year extension option exercisable at Shire's option, matures on November 2, 2016 (“November 2015 Facility A”), (ii) a \$2.2 billion amortizing term loan facility which matures on November 2, 2017 (“November 2015 Facility B”) and (iii) a \$2.4 billion amortizing term loan facility which matures on November 2, 2018 (“November 2015 Facility C”).

As of June 30, 2016, the November 2015 Facilities Agreement was fully utilized to finance the cash consideration payable and certain costs related to Shire's acquisition of Dyax.

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 of June 30, 2016 these Credit lines were not utilized.

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Capital Lease Obligations

The Group assumed certain capital lease obligations related to the Baxalta acquisition. These leases are primarily related to manufacturing facilities and as of June 30, 2016, the total capital lease obligation, including current portions, was \$348.9 million.

14. Retirement and Other Benefit Programs

As part of the acquisition of Baxalta, the Group assumed certain pension and other post-employment benefit (“OPEB”) plan obligations and plan assets. The following is a summary of the fair value of the pension and OPEB-related balances assumed as of June 3, 2016, the acquisition date.

(in millions)	U.S. Pension	International pension	OPEB
Projected Benefit Obligation and Plan Assets Assumed			
Projected benefit obligation	\$ 441.6	\$ 503.8	\$ 23.5
Plan assets	218.0	140.5	-
Funded status as of June 3, 2016	<u>\$(223.6)</u>	<u>\$(363.3)</u>	<u>\$(23.5)</u>
Amounts Recognized in the Consolidated Balance Sheet			
Other current liabilities	\$(0.2)	\$(3.1)	\$-
Other non-current liabilities	(223.4)	(360.2)	(23.5)
Net liability recognized as of June 3, 2016	<u>\$(223.6)</u>	<u>\$(363.3)</u>	<u>\$(23.5)</u>

The Group did not assume any gains or losses deferred in AOCI.

Accumulated Benefit Obligation Information

The pension obligation information in the table above represents the projected benefit obligation (“PBO”) assumed as of June 3, 2016. The PBO incorporates assumptions relating to future compensation levels. The accumulated benefit obligation (“ABO”) is the same as the PBO except that it includes no assumptions relating to future compensation levels. The ABO for all of the Group’s U.S. pension plans was \$369.2 million as of June 3, 2016. The ABO for all of the Group’s International pension plans was \$386.8 million as of June 3, 2016.

The information in the funded status table above represents the totals for all of the Group’s pension plans. The following is information relating to the individual plans as of June 3, 2016 in the funded status table above that have an ABO in excess of plan assets.

(in million)	June 3, 2016
U.S.	
ABO	\$ 369.2
Fair value of plan assets	218.0
International	
ABO	364.9
Fair value of plan assets	<u>\$ 118.2</u>

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Expected Net Pension and OPEB Plan Payments for the Next 10 Years

(in millions)	U.S. Pension	International pension	OPEB
2016 (after June 3, 2016)	\$ 0.9	\$ 7.3	\$ -
2017	3.6	14.7	0.2
2018	5.4	14.6	0.3
2019	7.3	16.2	0.4
2020	9.3	16.7	0.5
2021 through 2025	75.6	104.8	3.5
Total expected benefit payments for next 10 years	<u>\$ 102.1</u>	<u>\$ 174.3</u>	<u>\$ 4.9</u>

The expected net benefit payments above reflect the Group's share of the total net benefits expected to be paid from the plans' assets (for funded plans) or from the Group's assets (for unfunded plans). The federal subsidies relating to the Medicare Prescription Drug, Improvement and Modernization Act are not expected to be significant.

Net Periodic Benefit Cost

The net periodic benefit cost presented below is from the June 3, 2016 assumption of the obligations to June 30, 2016.

(in millions)	3 and 6 Months Ended June 30, 2016		
	U.S. Pension	International pension	OPEB
Net periodic benefit cost			
Service cost	\$ 1.9	\$ 2.6	\$ 0.1
Interest cost	1.6	0.4	0.1
Expected return on plan assets	(1.3)	(0.5)	-
Net periodic benefit cost	<u>\$ 2.2</u>	<u>\$ 2.5</u>	<u>\$ 0.2</u>

Weighted-Average Assumptions Used in Determining Benefit Obligations at the Measurement Date and Net Periodic Benefit Cost

	U.S. Pension	International pension	OPEB
Discount rate	4.1%	1.0%	4.2%
Rate of compensation increase	3.8%	3.2%	n/a
Annual rate of increase in the per-capita cost	n/a	n/a	6.5%
Rate decreased to	n/a	n/a	5.0%
by the year ended	n/a	n/a	2022

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The assumptions above, which were used in calculating the June 3, 2016 measurement date benefit obligations, are used in the calculation of net periodic benefit cost in 2016 along with the expected return on plan asset assumption. The Group establishes the expected return on plan assets assumption primarily based on a review of historical compound average asset returns, both Group-specific and relating to the broad market (based on the Group's asset allocation), as well as an analysis of current market and economic information and future expectations. The Group plans to use weighted-average assumptions of 7.0% and 4.5% for its U.S. and International funded plans, respectively, for the remainder of 2016.

Pension Plan Assets

A committee of members of senior management is responsible for supervising, monitoring and evaluating the invested assets of the Group's funded pension plans. The committee abides by policies and procedures relating to investment goals, targeted asset allocations, risk management practices, allowable and prohibited investment holdings, diversification, use of derivatives, the relationship between plan assets and benefit obligations, and other relevant factors and considerations. In the United States, Goldman Sachs Asset Management acts as an outsourced chief investment officer ("oCIO") to perform the day-to-day management of pension assets.

The policies and procedures include the following:

- Ability to pay all benefits when due;
- Targeted long-term performance expectations relative to applicable market indices, such as Standard & Poor's, Russell, MSCI EAFE, and other indices;
- Targeted asset allocation percentage ranges (summarized below), and periodic reviews of these allocations;
- Specified investment holding and transaction prohibitions (for example, private placements or other restricted securities, securities that are not traded in a sufficiently active market, short sales, certain derivatives, commodities and margin transactions);
- Specified portfolio percentage limits on holdings in a single corporate or other entity (generally 5%, except for holdings in U.S. government or agency securities);
- Specified average credit quality for the fixed-income securities portfolio (at least A- by Standard & Poor's or A3 by Moody's);
- Specified portfolio percentage limits on foreign holdings; and
- Periodic monitoring of oCIO performance and adherence to policies.

Plan assets are invested using a total return investment approach whereby a mix of equity securities, debt securities and other investments are used to preserve asset values, diversify risk and exceed the planned benchmark investment return. Investment strategies and asset allocations are based on consideration of plan liabilities, the plans' funded status and other factors, such as the plans' demographics and liability durations. Investment performance is reviewed on a quarterly basis and asset allocations are reviewed at least annually.

Plan assets are managed in a balanced equity and fixed income portfolio. The target allocations for plan assets are 75 percent in an equity portfolio and 25 percent in a fixed income portfolio. The documented policy includes an allocation range based on each individual investment type within the major portfolios that allows for a variance from the target allocations of approximately 5%. The equity portfolio may include common stock of U.S. and international companies, common/collective trust funds, mutual funds, hedge funds and real asset investments. The fixed income portfolio may include cash, money market funds with an original maturity of three months or less, U.S. and foreign government and governmental agency issues, common/collective trust funds, corporate bonds, municipal securities, derivative contracts and asset-backed securities.

While the committee provides oversight over plan assets for U.S. and international plans, the summary above is specific to the plans in the U.S. The plan assets for international plans are managed and allocated by the entities in each country, with input and oversight provided by the committee.

The following tables summarize the bases used to measure the pension plan assets and liabilities that are carried at fair value on a recurring basis for the U.S. funded plan.

(in millions)	Basis of fair value measurement			
	Balance at June 3, 2016	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets				
Fixed income				
Cash equivalents	\$ 4.4	\$ -	\$ 4.4	\$ -
Common/collective trust funds	53.4	-	53.4	-
Equity				
Common/collective trust funds	149.5	-	149.5	-
Hedge funds	10.7	-	10.7	-
Fair value of pension plan assets	<u>\$ 218.0</u>	<u>\$ -</u>	<u>\$ 218.0</u>	<u>\$ -</u>

The following tables summarize the bases used to measure the pension plan assets and liabilities that are carried at fair value on a recurring basis for the international funded plans.

(in millions)	Basis of fair value measurement			
	Balance at June 3, 2016	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets				
Fixed income				
Cash and cash equivalents	\$ 9.7	\$ 9.7	\$ -	\$ -
Government agency issues	1.5	1.5	-	-
Corporate bonds	30.1	30.1	-	-
Mutual funds	40.5	40.5	-	-
Equity				
Common stock:				
Large cap	15.7	15.7	-	-
Mid cap	1.6	1.6	-	-
Total common stock	<u>17.3</u>	<u>17.3</u>	<u>-</u>	<u>-</u>
Mutual funds	21.5	21.5	-	-
Real estate funds	10.2	8.4	1.8	-
Other holdings	9.7	0.1	9.6	-
Fair value of pension plan assets	<u>\$ 140.5</u>	<u>\$129.1</u>	<u>\$ 11.4</u>	<u>\$ -</u>

The assets and liabilities of the Group's pension plans are valued using the following valuation methods:

Investment category	Valuation methodology
Cash and cash equivalents	These largely consist of a short-term investment fund, U.S. dollars and foreign currency. The fair value of the short-term investment fund is based on the net asset value
Government agency issues	Values are based on quoted prices in an active market
Corporate bonds	Values are based on the valuation date in an active market
Common stock	Values are based on the closing prices on the valuation date in an active market on national and international stock exchanges
Mutual funds	Values are based on the net asset value of the units held in the respective fund which are obtained from national and international exchanges
Common/collective trust funds and hedge funds	Values are based on the net asset value of the units held at year end
Real estate funds	The value of these assets are either determined by the net asset value of the units held in the respective fund which are obtained from national and international exchanges or based on the net asset value of the underlying assets of the fund provided by the fund manager
Other holdings	The value of these assets vary by investment type and are primarily based on reputable pricing vendors that typically use pricing matrices or models

Expected Pension and OPEB Plan Funding

The Group's funding policy for its pension plans is to contribute amounts sufficient to meet legal funding requirements, plus any additional amounts that the Group may determine to be appropriate considering the funded status of the plans, tax deductibility, the cash flows generated by the Group, and other factors. Volatility in the global financial markets could have an unfavorable impact on future funding requirements. The Group has no obligation to fund its principal plans in the U.S. in 2016. The Group continually reassesses the amount and timing of any discretionary contributions. The Group expects to make cash contributions to its pension plans of at least \$4 million for the second half of 2016, primarily related to the Group's international plans. The Group expects to have net cash outflows relating to its OPEB plan of less than \$1 million for the second half of 2016.

The table below details the funded status percentage of the Group's assumed pension plans from Baxalta as of the acquisition date, including certain plans that are unfunded in accordance with the guidelines of the Group's funding policy outlined above.

(in millions, except percentages)	United States		International		Total
	Qualified plans	Nonqualified plans	Funded plans	Unfunded plans	
Fair value of plan assets	\$ 218.0	n/a	\$ 140.5	n/a	\$ 358.5
PBO	410.9	30.7	324.0	179.8	945.4
Funded status percentage	53%	n/a	43%	n/a	38%

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15. Accumulated Other Comprehensive Loss

The changes in accumulated other comprehensive loss, net of their related tax effects, for the six months ended June 30, 2016 and 2015 are included below:

(in millions)	Foreign currency translation adjustment	Unrealized holding loss on available- for-sale securities	Hedging activities	Accumulated other comprehensive loss
As of January 1, 2016	\$(182.1)	\$(1.7)	\$-	\$(183.8)
Net current period other comprehensive loss	(195.5)	(4.7)	(1.8)	(202.0)
As of June 30, 2016	<u>\$(377.6)</u>	<u>\$(6.4)</u>	<u>\$(1.8)</u>	<u>\$(385.8)</u>

(in millions)	Foreign currency translation adjustment	Unrealized holding (loss)/gain on available- for-sale securities	Hedging activities	Accumulated other comprehensive loss
As of January 1, 2015	\$(25.7)	\$(5.8)	\$ -	\$(31.5)
Net current period other comprehensive (loss)/income	(83.3)	3.3	-	(80.0)
As of June 30, 2015	<u>\$(109.0)</u>	<u>\$(2.5)</u>	<u>-</u>	<u>\$(111.5)</u>

Reclassifications out of AOCI and into earnings during the three and six months ended June 30, 2016 and June 30, 2015 were not material.

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16. Earnings per Share

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

(in millions)	3 Months Ended June 30,		6 Months Ended June 30,	
	2016	2015	2016	2015
Income from continuing operations, net of taxes	\$86.6	\$164.1	\$496.1	\$577.0
Loss from discontinued operations	(248.7)	(4.5)	(239.2)	(7.0)
Numerator for basic and diluted earnings per share	\$ (162.1)	\$ 159.6	\$ 256.9	\$ 570.0
Weighted average number of shares:				
(in millions)				
Basic	682.8	590.5	637.3	589.8
Effect of dilutive shares:				
Share-based awards to employees	-	2.7	2.8	3.2
Diluted	682.8	593.2	640.1	593.0

Weighted average number of basic shares excludes shares purchased by the Employee Benefit Trust ("EBT") and under the shares buy-back program are presented by Shire as treasury stock. Share-based awards to employees are calculated using the treasury method.

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

	3 Months Ended June 30,		6 Months Ended June 30,	
	2016	2015	2016	2015
	No. of shares	No. of shares	No. of shares	No. of shares
	(in millions)			
Share-based awards to employees	8.3	1.0	4.4	3.2

Certain stock options have been excluded from the calculation of diluted Earnings per Share ("EPS") for the six months ended June 30, 2016 and for the three and six months ended June 30, 2015 because either their exercise prices exceeded Shire's average share price during the calculation period or the required performance conditions were not satisfied as of the balance sheet date.

Stock options for the three months ended June 30, 2016 have been excluded from the calculation of diluted EPS because the inclusion of these shares would have been antidilutive.

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17. Taxation

For the three and six months ended June 30, 2016, the effective tax rate on income from continuing operations was -427% (2015: -37%) and 2% (2015: 2%), respectively.

The effective tax rate for the three and six months ended June 30, 2016 is affected by the combined impact of the relative quantum of the profit before tax for the period by jurisdiction and of the reversal of deferred tax liabilities from the Baxalta acquisition (including in higher tax territories such as the U.S.) of inventory and intangible assets amortization as well as significant acquisition and integration costs.

The effective tax rate for the three months ended June 30, 2015 was negative primarily due to the reduction in deferred tax liabilities in relation to the impairment of IPR&D intangible assets, the re-measurement of uncertain tax positions relating to ongoing tax audits and the release of certain valuation allowances all recognized during the second quarter of 2015.

The Group has historically calculated the provision for income taxes during interim reporting periods by applying an estimate of the annual effective tax rate for the full year to ordinary income or loss for the reporting period. For the three and six months ended June 30, 2016, the impact of certain items arising from the Baxalta acquisition has caused significant variations in the estimated effective tax rate when compared to the three and six months ended June 30, 2015. As a result, the Group has applied a permitted exception to the general rule by including the actual income tax effect of certain portions of its business discretely when calculating the provision for income taxes for the three and six months ended June 30, 2016.

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18. Segment Reporting

Shire operates as one 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.

For a more detailed description of segment disclosures about products, geographic areas and major customers, please read Note 24, Segmental Reporting, of the Group's Annual Report and Accounts for the year ended December 31, 2015.

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

(in millions)	6 Months Ended June 30,	
	2016	2015
Product sales:		
CINRYZE	\$ 337.2	\$ 286.9
ELAPRASE	277.6	271.5
FIRAZYR	265.0	196.6
REPLAGAL	221.6	214.4
VPRIV	171.6	171.1
KALBITOR	28.1	-
Genetic Diseases total	1,301.1	1,140.5
VYVANSE	1,026.9	841.6
ADDERALL XR	200.6	181.7
Other Neuroscience	57.8	52.4
Neuroscience total	1,285.3	1,075.7
LIALDA/MEZAVANT	361.7	306.4
PENTASA	136.9	145.0
GATTEX/REVESTIVE	96.2	52.2
NATPARA	35.5	5.9
Other Internal Medicine	173.3	173.7
Internal Medicine total	803.6	683.2
HEMOPHILIA	275.6	-
INHIBITOR THERAPIES	74.0	-
Hematology total	349.6	-
IMMUNOGLOBULIN THERAPIES	138.2	-
BIO THERAPEUTICS	51.3	-
Immunology total	189.5	-
Oncology total	20.3	-
Total product sales	3,949.4	2,899.4
Royalties and Other Revenues:		
SENSIPAR Royalties	73.5	45.2
3TC and ZEFFIX Royalties	27.1	18.0
FOSRENOL Royalties	20.6	19.2
ADDERALL XR Royalties	11.0	15.1
Other Royalties and Revenues	56.8	49.1
Total Royalties and Other Revenues	189.0	146.6
Total Revenues	\$ 4,138.4	\$ 3,046.0

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19. Commitments and Contingencies

Leases

Future minimum lease payments under operating leases as of June 30, 2016 are presented below:

(in millions)	Operating leases
2016 (remaining six months)	\$ 66.3
2017	102.3
2018	83.3
2019	71.3
2020	70.5
2021	67.7
Thereafter	299.2
	<hr/> \$760.6 <hr/>

The Group leases land, facilities, motor vehicles and certain equipment under operating leases expiring through 2039. For the three and six months ended June 30, 2016, lease and rental expense totaled \$22.8 million and \$30.3 million, respectively (2015: \$10.1 million and \$24.3 million, respectively), which is predominately included in SG&A expenses in the Group's Unaudited Consolidated Statements of Operations.

Letters of credit and guarantees

As of June 30, 2016, the Group had irrevocable standby letters of credit and guarantees with various banks and insurance companies totaling \$145.0 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.

On June 3, 2016, the Group provided a full and unconditional guarantee for Baxalta's obligations related to the Senior Notes.

Commitments

Clinical testing

At June 30, 2016, the Group had committed to pay approximately \$1,008 million (December 31, 2015: \$490 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.

Contract manufacturing

At June 30, 2016, the Group had committed to pay approximately \$447 million (December 31, 2015: \$325 million) in respect of contract manufacturing. The Group expects to pay \$213 million of these commitments in 2016.

Other purchasing commitments

At June 30, 2016, the Group had committed to pay approximately \$2,153 million (December 31, 2015: \$485 million) for future purchases of goods and services, predominantly relating to active pharmaceutical ingredients sourcing. The Group expects to pay \$865 million of these commitments in 2016.

Investment commitments

At June 30, 2016, the Group had outstanding commitments to purchase common stock and interests in companies and partnerships, respectively, for amounts totaling \$90 million (December 31, 2015: \$22 million) which may all be payable in 2016, depending on the timing of capital calls. The investment commitments include additional funding to certain VIEs for which Shire is not the primary beneficiary.

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Capital commitments

At June 30, 2016, the Group had committed to spend \$82 million (December 31, 2015: \$60 million) on capital projects.

Baxter related tax indemnification

Baxter and Baxalta entered into a tax matters agreement, effective on the date of Baxalta's separation from Baxter, which employs a direct tracing approach, or where direct tracing approach is not feasible, an allocation methodology, to determine which Group is liable for pre-separation income tax items for U.S. federal, state and foreign jurisdictions. With respect to tax liabilities that are directly traceable or allocated to Baxalta but for which Baxalta was not the primary obligor, Baxalta recorded a tax indemnification amount that would be due to Baxter upon Baxter discharging the associated tax liability to the taxing authority. At June 30, 2016, the amount of the net tax indemnification amount was \$37 million.

20. Legal and other proceedings

The Group expenses legal costs when 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 before the ultimate loss is known, and are therefore refined each accounting period as additional information becomes known. An outcome that deviates from the Group's estimate may result in an additional expense or release in a future accounting period. As of June 30, 2016, provision for litigation losses, insurance claims and other disputes totaled \$373.9 million (December 31, 2015: \$9.9 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.; 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 U.S. District Court for the District of New Jersey against the aforementioned parties (except Watson, who withdrew their ANDA).

On June 23, 2014, the U.S. 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. On September 24, 2015, the U.S. Court of Appeals of the Federal Circuit ("CAFC") affirmed that ruling against all of the ANDA filers and remanded the case to the trial court for further proceedings in which Shire expects the court to impose an injunction preventing all of the ANDA filers (Sandoz, Roxane, Amneal, Actavis and Mylan) from launching generic versions of VYVANSE until the expiration of these patents in 2023. The CAFC ruling overturned the infringement ruling against Johnson Matthey and the case against Johnson Matthey has been dismissed.

In March and April 2016, Shire received Notices of Allegation ("NOA") from Apotex Inc. ("Apotex") informing Shire that Apotex filed an Abbreviated New Drug Submission ("ANDS") with Health Canada seeking approval to market a generic version of VYVANSE in Canada. Within the requisite 45 days, Shire filed for an order of prohibition and, as a result, a 24-month stay of approval of the ANDS has been put into effect. On July 4, 2016, Apotex filed a Statement of Claim in Federal Court seeking a judicial declaration of invalidity and noninfringement of Shire's Canadian patent relating to VYVANSE. Shire is reviewing the Statement of Claim.

On April 14, 2016, Shire prevailed in upholding its European patent for ELVANSE. Shire initially prevailed in an opposition to its patent lodged by Johnson Matthey plc, Generics [UK] Limited (trading as Mylan) and Hexal AG and on April 14, 2016 Shire prevailed in the appeal. The decision by the appeals board of the European Patent Office is final and cannot be further appealed.

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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 U.S. 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. A trial took place between March 28, 2016 and April 1, 2016 and a decision is not expected before September 2016.

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 U.S. 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 U.S. District Court for the Southern District of Florida against Watson Laboratories Inc.—Florida and Watson Pharmaceuticals, Inc., Watson Pharma, Inc. and Watson Laboratories, Inc. (collectively, “Watson”) 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 and remanded the case to the U.S. District Court for the Southern District of Florida. A trial was held on January 25-27, 2016. A ruling was issued on March 28, 2016 upholding the validity of the patent and finding that Watson’s proposed ANDA product infringes the patent-in-suit. Watson appealed the ruling to the CAFC.

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 U.S. 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 to take place starting on September 6, 2016.

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 U.S. 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.

In September 2015, Shire was notified that Lupin Ltd. 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 U.S. District Court for the District of Maryland against Lupin Ltd., Lupin Pharmaceuticals Inc., Lupin Inc. and Lupin Atlantis Holdings SA. No trial date has been set. A Markman hearing is scheduled to take place on August 22, 2016.

On October 7, 2015 the Patent Trial and Appeals Board (“PTAB”) of the United States Patent Office instituted an inter partes review (“IPR”) of U.S. Patent 6,773,720 which is the patent-in-suit in the litigations referred to above. The IPR process is designed to re-assess the patentability of the claims of the patent. A decision from the PTAB is expected in October 2016.

Investigation related to DERMAGRAFT

The Department of Justice, including the U.S. Attorney’s Office for the Middle District of Florida, Tampa Division and the U.S. Attorney’s Office for Washington, DC, is conducting civil and criminal investigations into the sales and marketing practices of Advanced BioHealing Inc. (“ABH”) relating to DERMAGRAFT, which Shire acquired in June 2011. Following the disposal of the DERMAGRAFT business in January 2014, Shire retained certain legacy liabilities including any liability that may arise from this investigation.

Over the last several years, Shire has been cooperating fully with these investigations. As part of its efforts to cooperate, Shire has engaged in discussions with the Department of Justice about a possible resolution. As part of those discussions, during the quarter, Shire has reached an agreement on a proposal for a civil settlement in the amount of \$350 million plus interest, subject to negotiating a final settlement agreement and obtaining final approvals. As of June 30, 2016, an accrual has been recorded related to the settlement. Assuming the agreement

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is finalized, it will resolve the civil investigations conducted by the Department of Justice, including multiple U.S. Attorney's Offices and relevant federal and state agencies.

The tentative settlement proposal would settle the federal government's claims under the federal False Claims Act and the DERMAGRAFT Medicaid-related claims for states that opt into the settlement. Some states with DERMAGRAFT Medicaid-related claims might elect to opt out of any final settlement, and those states' claims would remain unresolved.

Material issues remain open and subject to further negotiation and approval by Shire, the Department of Justice and other relevant federal and state agencies before the tentative settlement can be finalized.

Civil Investigative Demand relating to VANCOCIN

On April 6, 2012, ViroPharma Incorporated ("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 has fully cooperated with the FTC's 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 on behalf of these patients to date, and moral damages associated with these claims.

On May 6, 2016, the trial court judge ruled on the case and dismissed all the claims under the class action, which decision has been appealed. A final decision is expected within the next 18 months

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21. Share-based compensation plans

Total share-based compensation recorded by the Group during the three and six months ended June 30, 2016 and June 30, 2015 by line item is as follows:

(in millions)	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Cost of sales	\$4.5	\$ 1.9	\$ 7.6	\$ 4.6
Research and development	13.6	9.1	25.2	17.6
Selling, general and administrative	14.4	10.9	23.6	13.3
Integration and acquisition costs	144.0	-	138.4	-
Reorganization costs	-	7.0	-	8.7
Total	176.5	28.9	194.8	44.3
Less tax	(41.5)	(7.9)	(46.3)	(12.0)
	\$135.0	\$21.0	\$148.5	\$32.3

The table above includes \$146.3 million of pre-tax expense during both the three and six months ended June 30, 2016, related to replacement and other awards held by Baxalta employees as further described below. Included in the \$146.3 million was an integration-related expense of \$138.4 million resulting from the acceleration of unrecognized expense associated with certain employee terminations.

Share-based compensation plans that existed as of December 31, 2015

Prior to February 28, 2015 the Group granted stock-settled share appreciation rights ("SARs") and performance share awards ("PSAs") over ordinary shares and ADSs to Executive Directors and employees under the Shire Portfolio Share Plan ("PSP") (Parts A and B). Since February 28, 2015 the Group has granted awards under the Shire Long Term Incentive Plan 2015 ("LTIP"). Under the LTIP the Group grants stock-settled SARs, restricted stock units ("RSUs") and performance share units ("PSUs") over ordinary shares and ADSs to Executive Directors and employees.

These plans and the underlying share-based award grants pursuant to the plans as of December 31, 2015 are further discussed in the Group's Annual Report and Accounts for the year ended December 31, 2015.

Replacement Awards Issued to Baxalta Employees

In connection with the acquisition of Baxalta and pursuant to the merger agreement associated with the acquisition, outstanding Baxalta equity awards held by Baxalta employees or employees of Baxter were cancelled and exchanged for Shire equity awards. The replacement Shire awards generally have the same terms and conditions (including vesting) as the former Baxalta awards for which they were exchanged. The value of the replacement share-based awards granted was designed to generally preserve the intrinsic value and the fair value of the award immediately prior to the acquisition.

Total replacement awards issued to Baxalta and Baxter employees on June 3, 2016 pursuant to the merger agreement were 22.2 million options and 3.9 million RSUs.

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The following table presents additional information regarding the replacement options issued as of June 3, 2016:

(options and aggregate intrinsic values in thousands)	Options*	Weighted-average exercise price	Weighted-average contractual term (in years)	Aggregate intrinsic value
Issued and outstanding	13,290	\$ 43.12	7.69	\$ 242,467
Vested and exercisable	5,691	\$ 40.72	6.12	\$ 117,453

*Number of awards are stated in terms of ordinary share equivalents

(number of RSUs in thousands)	RSUs*	Weighted average grant date fair value**
Issued and Outstanding	3,285	\$ 49.55

*Number of awards are stated in terms of ordinary share equivalents

**Reflects the pro rata portion representing future compensation as of June 3, 2016

Following the acquisition, the Group records share-based compensation expense associated with the acquisition-date fair value of acquired Baxalta employees' replacement options and RSUs that is attributable to post-acquisition service requirements, as well as share-based compensation expense for post-acquisition service requirements associated with certain remaining unvested Baxter share-based awards held by the acquired Baxalta employees. The portions of the acquisition-date fair values of the awards that are attributable to post-combination service are recognized over the remaining service period of the awards.

The weighted-average acquisition-date fair value and Black-Scholes assumptions related to replacement options issued to acquired Baxalta employees was as follows:

	As of June 3, 2016
Risk-free interest rate	1.20%
Expected dividend yield	0.35%
Expected life	3.9 years
Volatility	29.1%
Fair value per Option*	\$ 79.31

*Pro-rata portion of the fair value recognized as expense related to post combination service period

Total unrecognized expense related to the replacement options issued to acquired Baxalta employees of \$69.4 million is expected to be recognized over a weighted-average period of 1.5 years. Total unrecognized expense related to the replacement RSUs issued to acquired Baxalta employees of \$96.8 million is expected to be recognized over a weighted-average period of 2.1 years.

22. Related Parties

ArmaGen, Inc. ("ArmaGen") is a related party as the Group owns 21% of ArmaGen common stock and the parties have a worldwide licensing and collaboration agreement to develop and commercialize AGT-182. For the three and six months ended June 30, 2016, Shire recorded R&D costs arising from the licensing and collaboration arrangement of \$1.2 million and \$1.7 million, respectively (2015: \$5.5 million and \$5.9 million, respectively), of which \$0.3 million was accrued and unpaid as of June 30, 2016 (2015: \$5.4 million).

23. Agreements and Transactions with Baxter

In connection with the Baxalta's separation from Baxter on July 1, 2015, Baxalta and Baxter entered into several separation-related agreements that provided a framework for Baxalta's relationship with Baxter after the separation. As a result of the acquisition of Baxalta, the Group became party to the separation-related agreements with Baxter. These agreements, among others, included a manufacturing and supply agreement, a transition services agreement, an international commercial operations agreement and tax matters agreement.

Under the terms of the manufacturing and supply agreement, the Group manufactures certain products and materials and sells them to Baxter at an agreed-upon price reflecting the Group's cost plus a mark-up for certain products and materials. The Group reported revenues associated with the manufacturing and supply agreement with Baxter of approximately \$16 million for both the three and six months ended June 30, 2016.

Under the terms of the transition services agreement, the Group and Baxter provide various services to each other on an interim, transitional basis. The services provided by Baxter to the Group include certain finance, information technology, human resources, quality, supply chain and other administrative services and functions, and are generally provided on a cost-plus basis. The services generally extend for approximately 2 years following the July 1, 2015 separation except for certain information technology services that may extend for 3 years following the July 1, 2015 separation. The Group reported SG&A expenses of approximately \$8 million associated with the transition services agreement with Baxter for both the three and six months ended June 30, 2016.

For a certain portion of Baxalta's non U.S. operations, the legal transfer of net assets from Baxter had not occurred by the June 3, 2016 acquisition date due to the time required to transfer marketing authorizations and other regulatory requirements in each of these countries. Under the terms of the international commercial operations agreement with Baxter, the Group is responsible for the business activities conducted by Baxter on its behalf, and is subject to the risks and entitled to the benefits generated by these operations and assets. As a result, the related assets and liabilities and results of operations are reported in the Group's consolidated financial statements following the acquisition of Baxalta. The Group reported net sales related to these operations of \$22 million for both the three and six months ended June 30, 2016. As of June 30, 2016, the assets and liabilities of these operations consisted of inventories of \$26 million, which are reported in inventories on the consolidated balance sheet, other assets of \$68 million, which are reported as prepaid expenses and other current assets, and liabilities of \$4 million, which are reported in other current liabilities. The majority of these operations are expected to be transferred to the Group by the end of 2016.

The tax matters agreement governs Baxter and Baxalta's and now the Group's respective rights, responsibilities and obligations after the distribution with respect to taxes for any tax period ending on or before the distribution date, as well as tax periods beginning before and ending after the distribution date. In addition, the tax matters agreement addresses the allocation of liability for taxes that were incurred as a result of restructuring activities undertaken to effectuate the distribution and provides for Baxalta to indemnify Baxter against any tax liabilities resulting from Baxalta's action or inaction that causes the merger-related transactions to be taxable. Net tax-related indemnification liabilities reported by the Group as of June 30, 2016 are further discussed in Note 19, Commitments and Contingencies, of these Unaudited Consolidated Financial Statements.

As of June 30, 2016, the Group had amounts due from or to Baxter of \$278 million reported in prepaid expenses and other current assets, \$34 million reported in other noncurrent assets, \$138 million reported in other current liabilities and \$95 million reported in other noncurrent liabilities. These balances included the net tax-related indemnification liabilities, as further discussed above.

24. Subsequent Events

On June 14, 2016, Shire announced it agreed to license global rights, subject to regulatory approvals, to all indications for SHP647 (formerly PF-00547659) from Pfizer Inc. SHP647 is an investigational biologic being evaluated for the treatment of moderate-to-severe inflammatory bowel disease. Regulatory approval was received and the transaction closed on July 1, 2016. Under the terms of the agreement, Pfizer received an upfront payment of \$90 million and is eligible to receive milestone payments based on clinical, regulatory and commercial milestones and royalties based on net sales if the product is approved.

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 CER*; *Non GAAP net debt*, *Non GAAP EBITDA*.

The Non GAAP measures exclude the impact of certain specified items that are highly variable, difficult to predict, and of a size that may substantially impact Shire’s operations. Upfront and milestone payments related to in-licensing and acquired products that have been expensed as R&D are also excluded as specified items as they are generally uncertain and often result in a different payment and expense recognition pattern than ongoing internal R&D activities. Intangible asset amortization has been excluded from certain measures to facilitate an evaluation of current and past operating performance, particularly in terms of cash returns, and is similar to how management internally assesses performance. The Non GAAP financial measures are presented in this Half-yearly Report as Shire’s management believes that they will provide investors with an additional analysis of Shire’s results of operations, particularly in evaluating performance from one period to another.

Shire’s management uses Non GAAP financial measures to make operating decisions as they facilitate additional internal comparisons of Shire’s performance to historical results and to competitor’s results, and provides them to investors as a supplement to Shire’s reported results to provide additional insight into Shire’s operating performance. Shire’s Remuneration Committee uses certain key Non GAAP measures when assessing the performance and compensation of employees, including Shire’s executive directors.

The Non GAAP financial measures used by Shire may be calculated different from, and therefore may not be comparable to, similarly titled measures used by other companies - refer to the section “Non GAAP Financial Measure Descriptions” below for additional information. In addition, these Non GAAP financial measures should not be considered in isolation as a substitute for, or as superior to, financial measures calculated in accordance with US GAAP, and Shire’s financial results calculated in accordance with US GAAP and reconciliations to those financial statements should be carefully evaluated.

Non GAAP Financial Measure Descriptions

Where applicable the following items, including their tax effect, have been excluded when calculating Non GAAP earnings and from our outlook:

Amortization and asset impairments:

- Intangible asset amortization and impairment charges; and
- Other than temporary impairment of investments.

Acquisitions and integration activities:

- Up-front payments and milestones in respect of in-licensed and acquired products;
- Costs associated with acquisitions, including transaction costs, fair value adjustments on contingent consideration and acquired inventory;
- Costs associated with the integration of companies; and
- Noncontrolling interests in consolidated variable interest entities.

Divestments, reorganizations and discontinued operations:

- Gains and losses on the sale of non-core assets;
- Costs associated with restructuring and reorganization activities;
- Termination costs; and
- Income/(losses) from discontinued operations.

Legal and litigation costs:

- Net legal costs related to the settlement of litigation, government investigations and other disputes (excluding internal legal team costs).

Additionally, in any given period Shire may have significant, unusual or non-recurring gains or losses which it may exclude from its Non GAAP earnings for that period. When applicable, these items would be fully disclosed and incorporated into the required reconciliations from US GAAP to Non GAAP measures.

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

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

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

Half-yearly Report



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

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

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

Independent review report to Shire plc

We have been engaged by Shire plc to review the condensed set of financial statements for Shire plc and its subsidiaries (the "Group") in the Half-yearly financial report for the six months ended 30 June 2016 which comprises the consolidated balance sheets, consolidated statements of operations, consolidated statements of comprehensive income, consolidated statement of changes in equity, the consolidated statements of cash flows and related notes 1 to 24. 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 group 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 group 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 group, 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 Group 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 2016 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
London, United Kingdom
5 August, 2016