GLAXOSMITHKLINE PLC
Form 20-F
February 27, 2015
Table of Contents

As filed with the Securities and Exchange Commission on February 27, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

¨ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2014

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

¨ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 1-15170

GlaxoSmithKline plc

(Exact name of Registrant as specified in its charter)

England

(Jurisdiction of incorporation or organization)

980 Great West Road, Brentford, Middlesex TW8 9GS England

(Address of principal executive offices)

Victoria Whyte

Company Secretary

GlaxoSmithKline plc

980 Great West Road

Brentford, TW8 9GS

England

+44 20 8047 5000

company.secretary@gsk.com

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange On Which Registered
American Depositary Shares, each representing	
2 Ordinary Shares, Par value 25 pence	**New York Stock Exchange**
0.750% Notes due 2015	**New York Stock Exchange**
0.700% Notes due 2016	**New York Stock Exchange**
1.500% Notes due 2017	**New York Stock Exchange**
5.650% Notes due 2018	**New York Stock Exchange**
2.850% Notes due 2022	**New York Stock Exchange**
2.800% Notes due 2023	**New York Stock Exchange**
6.375% Notes due 2038	**New York Stock Exchange**
4.200% Notes due 2043	**New York Stock Exchange**

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

(Title of class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

(Title of class)

Indicate the number of outstanding shares of each of the issuer s classes of capital or common stock as of the close of the period covered by the annual report.

Ordinary Shares of Par value 25 pence each **5,355,297,232**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

x Yes ¨ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

¨ Yes x No

Note Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

x Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

¨ Yes ¨ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ¨ International Financial Reporting Standards as issued Other ¨

by the International Accounting Standards Board x

If Other has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ¨ Item 18 ¨

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

¨ Yes x No

Table of Contents

TABLE OF CONTENTS

EX-15.2

1

Table of Contents

Pursuant to Rule 12b-23(a) of the Securities Exchange Act of 1934, as amended, the information for the 2014 Form 20-F of GlaxoSmithKline plc set out below is being incorporated by reference from the GSK Annual Report 2014 included as exhibit 15.2 to this Form 20-F dated and submitted on February 27, 2015 (the GSK Annual Report 2014).

All references in this Form 20-F to GlaxoSmithKline, the Group, GSK, we or our mean GlaxoSmithKline plc an subsidiaries; the company means GlaxoSmithKline plc.

References below to major headings include all information under such major headings, including subheadings, unless such reference is a reference to a subheading, in which case such reference includes only the information contained under such subheading.

In addition to the information set out below, the information set forth under the headings Cautionary statement on page 1 and the inside back cover, Directors Report on page 95, Directors statement of responsibilities on pages 130 and 211, Share buy-back programme on page 242, Annual General Meeting 2015 on page 245, Financial calendar , Results announcements and Financial reports on page 246, Section 13(r) of the US Securities Exchange Act on page 248, Registrar on page 249, ADR Depositary , Glaxo Wellcome and SmithKline Beecham Corporate PEPs , Donating shares to Save the Children , Contacts , Share scam alert and Responsible Business Supplement on page 250 and Glossary of terms on page 251 in each case of the GSK Annual Report 2014 is incorporated by reference.

Notice regarding limitations on Director Liability under English Law

Under the UK Companies Act 2006, a safe harbour limits the liability of Directors in respect of statements in and omissions from certain portions of the GSK Annual Report 2014 incorporated by reference herein, namely the Directors Report (for which see page 95 thereof), the Strategic Report (pages 2 to 70 thereof, portions of which are incorporated by reference as described below) and the Remuneration Report (pages 96 to 128 thereof). These reports have been drawn up and presented in accordance with, and in reliance upon, English company law. Under English law, the Directors would be liable to the company, but not to any third party, if these sections of the GSK Annual Report 2014 contain errors as a result of recklessness or knowing misstatement or dishonest concealment of a material fact, but would not otherwise be liable.

Portions of the GSK Annual Report 2014 incorporated by reference herein contain references to our website. Information on our website or any other website referenced in the GSK Annual Report 2014 is not incorporated into this Form 20-F and should not be considered to be part of this Form 20-F. We have included any website as an inactive textual reference only.

PART I

Item 1. **Identity of Directors, Senior Management and Advisers**
Not applicable.

Item 2. **Offer Statistics and Expected Timetable**
Not applicable.

Item 3. **Key Information**

3.A Selected financial data

The information set forth under the heading:

Five year record	on pages 222 to 224; and
Dividends	on page 244.

of the GSK Annual Report 2014 is incorporated herein by reference.

3.B Capitalization and indebtedness

Not applicable.

Table of Contents

3.C Reasons for the offer and use of proceeds

Not applicable.

3.D Risk factors

Principal risk factors and uncertainties

The principal risks discussed below are the risks and uncertainties relevant to our business, financial condition and results of operations that may affect our performance and ability to achieve our objectives. The factors below are those that we believe could cause our actual results to differ materially from expected and historical results.

We operate on a global basis in an industry that is both highly competitive and highly regulated. Our competitors may make significant product innovations and technical advances and may intensify price competition. In light of this competitive environment, continued development of commercially viable new products and the development of additional uses for existing products are critical to our ability to maintain or increase overall sales.

Developing new pharmaceutical, vaccine and consumer healthcare products is a costly, lengthy and uncertain process, however, and a product candidate may fail at any stage, including after significant Group economic and human resources have been invested. Our competitors products or pricing strategies or any failure on our part to develop commercially successful products, or to develop additional uses for existing products, could materially and adversely affect our financial results.

We must also adapt to and comply with a broad range of laws and regulations. These requirements apply to research and development, manufacturing, testing, approval, distribution, sales and marketing of Pharmaceutical, Vaccine and Consumer Healthcare Products, and affect not only the cost of product development but also the time required to reach the market and the uncertainty of successfully doing so.

Moreover, as rules and regulations change, and governmental interpretation of those rules and regulations evolves, the nature of a particular risk may change. Changes to certain regulatory regimes may be substantial. Any change in, and any failure to comply with, applicable law and regulation could materially and adversely affect our financial results.

Similarly, our business exposes us to litigation and government investigations, including but not limited to product liability litigation, patent and antitrust litigation and sales and marketing litigation. Litigation and government investigations, including related provisions we may make for unfavourable outcomes and increases in related costs such as insurance premiums, could materially and adversely affect our financial results. More detail on the status and various uncertainties involved in the significant unresolved disputes and potential litigation is set out in Note 45, Legal proceedings, on pages 206 to 210 of the GSK Annual Report 2014.

Failure to appropriately collect, review, follow up, or report adverse events from all potential sources, and to act on any relevant findings in a timely manner.

Risk impact

The impact of this risk is potentially to compromise our ability to conduct robust safety signal detection and interpretation and to ensure that appropriate decisions are taken with respect to the risk/benefit profile of our products, including the completeness and accuracy of product labels and the pursuit of additional studies/analyses, as appropriate. This could lead to potential harm to patients, reputational damage, product liability claims or other

litigation, governmental investigation, regulatory action such as fines, penalties or loss of product authorisation.

Context

Pre-clinical and clinical trials are conducted during the development of investigational Pharmaceutical, Vaccine and Consumer Healthcare Products to determine the safety and efficacy of the products for use by humans. Notwithstanding the efforts we make to determine the safety of our products through appropriate pre-clinical and clinical trials, unanticipated side effects may become evident only when products are widely introduced into the marketplace. Questions may be raised not only by our ongoing safety surveillance and post-marketing studies but also by governmental agencies and third-parties that may analyse publicly available clinical trial results.

Table of Contents

The Group is currently a defendant in a number of product liability lawsuits, including class actions, that involve significant claims for damages related to our products. Litigation, particularly in the US, is inherently unpredictable. Class actions that seek to sweep together all persons who were prescribed our products increase the potential liability. Claims for pain and suffering and punitive damages are frequently asserted in product liability actions and, if allowed, can represent potentially open-ended exposure and thus, could materially and adversely affect the Group s financial results.

Failure to appropriately secure and protect intellectual property rights.

Risk impact

Any failure to obtain or subsequent loss of patent protection, including reducing the availability or scope of patent rights or compulsory licensing (in which a government forces a manufacturer to license its patents for specific products to a competitor), could materially and adversely affect our financial results in those markets. Absence of adequate patent or data exclusivity protection could limit the opportunity to rely on such markets for future sales growth for our products, which could also materially and adversely affect our financial results.

Context

As an innovative Pharmaceutical, Vaccine and Consumer Healthcare Products company, we seek to obtain appropriate intellectual property protection for our products. Our ability to obtain and enforce patents and other proprietary rights with regard to our products is critical to our business strategy and success. Pharmaceutical and Vaccine products are usually only protected from being copied by generic manufacturers during the period of exclusivity provided by an issued patent or related intellectual property rights such as Regulatory Data Protection or Orphan Drug status. Following expiration of certain intellectual property rights, a generic manufacturer may lawfully produce a generic version of the product.

We operate in markets where intellectual property laws and patent offices are still developing and where governments may be unwilling to grant or enforce intellectual property rights in a fashion similar to more developed regions such as the EU, Japan and the US. Some developing countries have limited, or threatened to limit, effective patent protection for pharmaceutical products generally, or in particular therapeutic areas, in order to facilitate early competition within their markets from generic manufacturers.

We face competition from manufacturers of proprietary and generic pharmaceutical products in all of our major markets. Introduction of generic products, particularly in the US where we have our highest turnover and margins, typically leads to a rapid and dramatic loss of sales and reduces our revenues and margins for our proprietary products. In 2014, we had nine Pharmaceutical and Vaccine products with over £500 million in annual global sales. For certain of these products, there is generic competition in the US and some markets in Europe. We may also experience an impact on sales of one of our products due to the expiry or loss of patent protection for a product marketed by a competitor in a similar product class or for treatment of a similar disease condition.

We depend on certain key products for a significant portion of our sales. One such product is our respiratory pharmaceutical product Seretide/Advair which accounts for 18% of Group sales worldwide. The timing and impact of entry in the US for a generic product containing the same combination of active substances as Seretide/Advair is uncertain. The US patent for compositions containing the combination of active substances in Seretide/Advair expired during 2010 although the US patent on a component of the Advair Diskus device continues until August 2016. Generic products containing the same combination of active substances as Seretide/Advair (in both metered dose inhalers and dry powder inhalers) have been launched by several manufacturers in a number of European markets. The

timing and impact of entry in the US and major markets in Europe for a follow-on product to Seretide/Advair is uncertain.

Generic drug manufacturers have also exhibited a readiness to market generic versions of many of our most important products prior to the expiration of our patents. Their efforts may involve challenges to the validity or enforceability of a patent or assertions that their generic product does not infringe our patents. As a result, we are and may continue to be involved in legal proceedings involving patent challenges, which may materially and adversely affect our financial results. Moreover, in the US, it has become increasingly common for patent infringement actions to prompt claims that anti-trust laws have been violated during the prosecution of the patent or during litigation involving the defence of that patent. Such claims by direct and indirect purchasers and other payers are typically filed as class actions. The relief sought may include treble damages and restitution claims. Similarly, anti-trust claims may be brought by

Table of Contents

government entities or private parties following settlement of patent litigation, alleging that such settlements are anti-competitive and in violation of anti-trust laws. A successful anti-trust claim by a private party or government entity could materially and adversely affect our financial results.

The expiration dates for patents for our major products which may affect the dates on which generic versions of our products may be introduced are set out on pages Pharmaceutical products, competition and intellectual property on pages 229 to 231 of the GSK Annual Report 2014. Legal proceedings involving patent challenges are set out in Note 45, Legal proceedings, on pages 206 to 210 of the GSK Annual Report 2014.

Failure to comply with current Good Manufacturing Practice (cGMP) requirements in commercial manufacture, through the distribution chain, by GSK, its contractors or suppliers; or through inadequate controls and governance of quality through product development, and in supporting regulated activities.

Risk impact

A failure to ensure product quality could have far reaching implications in terms of patient and consumer safety, delays in launching new products, drug shortages, product recalls, potential damage to our reputation and that of the relevant product, as well as regulatory, legal, and financial consequences, which could materially and adversely affect our reputation and financial results.

Context

Patients, consumers and healthcare professionals trust the quality of our products. A failure to ensure product quality is an enterprise risk which is applicable across all of our business activities. Product quality may be influenced by many factors including product and process understanding, supply chain security, consistency of manufacturing components, compliance with GMP, accuracy of labeling, reliability of the external supply chain, and the embodiment of an overarching quality culture. The internal and external environment continues to evolve as new products, new markets and new legislation are introduced, particularly around security of supply, good distribution practice and product standards. Inspectional trending from national authorities during 2014 has highlighted a focus on issues relating to data integrity, contamination and the robustness of quality investigations.

Failure to deliver a continuous supply of compliant finished product.

Risk impact

A material interruption of supply or exclusion from healthcare programmes could impact patient access to our products, expose us to litigation or regulatory action and materially and adversely affect our financial results. In particular, the incurring of fines or disgorgement as a result of noncompliance with manufacturing practice regulations could also materially and adversely affect the Group s financial results and result in reputational damage.

Context

Our supply chain operations are subject to review and approval by various regulatory agencies that effectively provide our licence to operate. Failure by our manufacturing and distribution facilities or by suppliers of key services and materials could lead to litigation or regulatory action such as product recalls and seizures, interruption of supply, delays in the approval of new products, and suspension of manufacturing operations pending resolution of manufacturing or logistics issues. In 2014, our Consumer Healthcare business, particularly our Smokers Health products, alli and Bactroban, were impacted by various supply issues and our Vaccines business, particularly our

hepatitis vaccines and Boostrix, were impacted by supply constraints.

Materials and services provided by third-party suppliers are necessary for the commercial production of our products, including active pharmaceutical ingredients (API), antigens, intermediates, commodities and components necessary for the manufacture and packaging of many of our Pharmaceutical, Vaccine and Consumer Healthcare Products. Some of the third-party services procured, such as services provided by contract manufacturing organizations and clinical research organisations to support development of key products, are important to ensure continuous operation of our businesses. Although we undertake business continuity planning, single sourcing of certain components, bulk API, finished products, and services creates a risk of failure of supply in the event of regulatory non-compliance or physical disruption at the manufacturing sites or logistics system.

The failure of a small number of single-source, third-party suppliers or service providers to fulfill their contractual obligations in a timely manner or as a result of regulatory non-compliance or physical disruption of logistics and manufacturing sites may result in delays or service interruptions.

Table of Contents

Failure to report accurate financial information and material events in compliance with accounting standards and applicable legislation.

Risk impact

Non-compliance with existing or new financial reporting and disclosure requirements, or changes to the recognition of income and expenses, could expose us to litigation and regulatory action and could materially and adversely affect our financial results.

Context

New or revised accounting standards, rules and interpretations issued from time to time by the International Accounting Standards Board could result in changes to the recognition of income and expense that may materially and adversely affect our financial results.

The Group is also required by the laws of various jurisdictions to disclose publicly its financial results and events that could materially affect the financial results of the Group. Regulators routinely review the financial statements of listed companies for compliance with accounting and regulatory requirements. The Group believes that it complies with the appropriate regulatory requirements concerning our financial statements and disclosure of material information. However, should we be subject to an investigation into potential non-compliance with accounting and disclosure requirements, there is potential for restatements of previously reported results and we could be subject to significant penalties.

Failure to comply with current tax law, or react to the rapidly evolving tax environment. Incurring significant losses due to treasury activities.

Risk impact

Changes in tax laws or in their application with respect to matters such as transfer pricing, foreign dividends, controlled companies, R&D tax credits, taxation of intellectual property or a restriction in tax relief allowed on the interest on intra-group debt, could impact our effective tax rate. Significant losses may arise from Treasury activities through inconsistent application of Treasury policies, dealing or settlement errors, or counterparty defaults. Any such changes in tax laws or their application, failure to comply with tax law or significant losses due to treasury activities could materially and adversely affect our financial results.

Context

Our Treasury group deals in high value transactions, mostly foreign exchange and cash management transactions, on a daily basis. The Group s effective tax rate is driven by rates of tax in jurisdictions that are both higher and lower than the UK. In addition, many jurisdictions currently offer regimes that encourage innovation and investment in science by providing tax incentives, such as R&D tax credits and lower tax rates on income derived from patents. Furthermore, as an international business, we face risks associated with intra-group transfer pricing.

The tax charge included in our financial statements is our best estimate of tax liability pending audits by tax authorities. We submit tax returns according to statutory time limits and engage tax authorities to help ensure our tax affairs are current. In exceptional cases where matters cannot be settled by agreement with tax authorities, we may have to resolve disputes through formal appeals or other proceedings. As an international business, we are also subject to a range of other duties and taxes carrying similar types of risk.

There is an increased focus on the tax position of multinational businesses, as a consequence of the challenging economic environment and the priority placed by the G20 on addressing allegations of unlawful tax avoidance. We have seen some increase in audits as governments seek to raise revenues, both from corporate taxes and above the line taxes such as customs duties. Such audits regardless of their merit or outcomes can be costly, divert management attention and may adversely impact our reputation. In addition, there are an increasing number of changes to the international tax framework which could lead to an increase or decrease in our tax costs.

There is a risk that GSK personnel, or third parties acting on our behalf, seek to induce improper performance of someone s role in order to gain or retain GSK a business advantage through the offer, promise or giving of a bribe. This goes against our ethical standards and is contrary to the laws by which we are bound.

Table of Contents

Risk impact

Failure to mitigate this risk could expose the Group and associated persons to governmental investigation, regulatory action and civil and criminal liability, as well as damage the Group s reputation, shareholder value, and our licence to operate in particular jurisdictions, all of which could materially and adversely affect our financial results.

Context

We are exposed to bribery and corruption risk through our global business operations. In some markets, the government structure and the rule of law are less developed, and this has a bearing on our bribery and corruption risk exposure. In addition to the global nature of our business, the healthcare sector is highly competitive and subject to regulation. This increases the instances where we are exposed to activities and interactions with bribery and corruption risk.

As has previously been disclosed, the Group in 2014 has been subject to regulatory action and media focus with regard to bribery investigations in China and other markets. On 19 September 2014, the Group announced that the Changsha Intermediate People s Court in Hunan Province, China ruled that, according to Chinese law, GSK China Investment Co. Ltd (GSKCI), had offered money or property to non-government personnel in order to obtain improper commercial gains, and been found guilty of bribing non-government personnel. The verdict followed investigations initiated by China s Ministry of Public Security in June 2013. As a result of the Court s verdict, GSKCI has paid a fine of RMB 3 billion (£301 million) to the Chinese government.

The US and UK authorities are leading extra-territorial ABAC inquires into certain of the Group s operations. These investigations are further discussed in Note 45, Legal proceedings, on pages 206 to 210 of the GSK Annual Report 2014.

Failure to engage in commercial and/or scientific activities that are consistent with the letter and spirit of legal, industry, or the Group s requirements relating to marketing and communications about our medicines and associated therapeutic areas; appropriate interactions with healthcare professionals (HCPs) and patients; and legitimate and transparent transfer of value.

Risk impact

Failure to comply with applicable laws, rules and regulations may result in governmental investigation, regulatory action and legal proceedings brought against the Group by governmental and private plaintiffs. Failure to provide accurate and complete information related to our products may result in incomplete awareness of the benefit: risk profile of our medicines and possibly suboptimal treatment of patients. Any of these consequences could materially and adversely affect our financial results. Any practices that are found to be misaligned with our values could also result in reputational damage and dilute trust established with key stakeholders. In 2012, we paid $3 billion to resolve government investigations in the US focused in large part on promotional practices.

Context

We are committed to legitimate Scientific Engagement and the ethical and responsible commercialisation of medicines to support our mission to improve the quality of human life by enabling people to do more, feel better, and live longer. To accomplish this mission, we engage the healthcare community in various ways to advance our scientific knowledge as well as to provide important information about our medicines.

The Group disseminates information about its products through both non-promotional Scientific Engagement and promotional activities. The former is the interaction and exchange of information between the Group and partners and external communities in order to advance scientific and medical understanding including the appropriate development and use of our products; the management of disease; and patient care. It is distinct from promotional activities which may take place only after authorisation of a new product or indication, and must be conducted strictly in accordance with promotional laws, codes and the Group s Policy.

Promotion of approved medicines helps ensure that HCPs globally have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients. We are committed to communicating information related to our approved products in a responsible, legal, and ethical manner.

At times, researchers, HCPs, healthcare organisations (HCOs) and other external experts that we engage may be compensated for services and expertise provided. However, payments must not be excessive and must never be or be perceived to be an inducement or reward for prescribing our products. Consistent with our ABAC policies, they also must comply with a market s ABAC laws if the recipient of any payment is a government official.

Table of Contents

Failure adequately to protect and inform patients involved in human clinical trial research; conduct objective, ethical preclinical and clinical trials using sound scientific principles; guarantee the integrity of discovery, preclinical, and clinical development data; manage human biological samples according to established ethical standards and regulatory expectations; treat animals ethically and practice good animal welfare; appropriately disclose human subject research for medicinal products; and ensure the integrity of our regulatory filings and of the data that we publish.

Risk impact

The impacts of the risk include harm to patients, reputational damage, failure to obtain the necessary regulatory approvals for our products, governmental investigation, legal proceedings (product liability suits and claims for damages), and regulatory action such as fines, penalties or loss of product authorisation, which could materially and adversely affect our financial results.

Context

Research relating to animals can raise ethical concerns. While we attempt to proactively address this, animal studies remain a vital part of our research. In many cases, they are the only method that can be used to investigate the effects of a potential new medicine in a living body before it is tested in humans, and they are generally mandated by regulators and ethically imperative. Animal research can provide critical information about the causes of diseases and how they develop. Some countries require additional animal testing even when medicines have been approved for use elsewhere.

Clinical trials in healthy volunteers and patients are used to assess and demonstrate an investigational product s efficacy and safety or further evaluate the product once it has been approved for marketing. We also work with human biological samples. These samples are fundamental to the discovery, development and safety monitoring of our products.

The integrity of our data is essential to success in all stages of the research data lifecycle: design, generation, recording and management, analysis, reporting and storage and retrieval. Our research data is governed by legislation and regulatory requirements.

Research data and supporting documents are core components at various stages of pipeline progression decision-making and also form the content of regulatory submissions. Poor data integrity can compromise our research efforts.

There are innate complexities and interdependencies required for regulatory filings, particularly given our global research and development footprint. Rapid changes in submission requirements in developing countries continue to increase the complexity of worldwide product registration.

Failure to manage environment, health and safety and sustainability (EHSS) risks consistent with the Group s ethics, objectives, policies and relevant laws and regulations.

Risk impact

Failure to manage EHSS risks could lead to significant harm to people, the environment and communities in which we operate, fines, failure to meet stakeholder expectations and regulatory requirements, litigation or regulatory action, and damage to the Group s reputation and could materially and adversely affect our financial results.

Context

The Group is subject to health, safety and environmental laws of various jurisdictions. These laws impose duties to protect people, the environment and the communities in which we operate as well as potential obligations to remediate contaminated sites. We have also been identified as a potentially responsible party under the US Comprehensive Environmental Response Compensation and Liability Act at a number of sites for remediation costs relating to our use or ownership of such sites. Failure to manage these environmental risks properly could result in litigation, regulatory action and additional remedial costs that may materially and adversely affect our financial results. See Note 45 to the financial statements, Legal proceedings , for a discussion of the environmental related proceedings in which we are involved. We routinely accrue amounts related to our liabilities for such matters.

Risk to the Group s business activity if critical or sensitive computer systems or information are not available when needed, are accessed by those not authorised, or are deliberately changed or corrupted.

Table of Contents

Risk impact

Failure to adequately protect critical and sensitive systems and information may result in our inability to maintain patent rights, loss of commercial or strategic advantage, damage to our reputation or business disruption including litigation or regulatory sanction and fines, which could materially and adversely affect our financial results.

Context

We rely on critical and sensitive systems and data, such as corporate strategic plans, sensitive personally identifiable information, intellectual property, manufacturing systems and trade secrets. There is the potential that malicious or careless actions expose our computer systems or information to misuse or unauthorised disclosure.

Inability to recover and sustain critical operations following a disruption or to respond to a crisis incident in a timely manner.

Risk impact

Failure to manage crisis and continuity management (CCM) effectively can lead to prolonged business disruption, greater damage to the Group s assets, and risk of supply disruption to patients of a medicine, any of which could materially and adversely affect our financial results. Delays to operational activities and delivery of our products to consumers and patients who rely on them could also expose us to litigation or regulatory action, materially and adversely affect our financial results and lead to reputational damage.

Context

The Group s international operations, and those of its partners, maintain a vast global footprint exposing our workforce, facilities, operations and information technology to potential disruption resulting from a natural event (e.g., storm or earthquake), a man-made event (e.g., civil unrest, terrorism), or a global emergency (e.g., Ebola outbreak, Flu pandemic). Through effective crisis management and business continuity planning we are committed to providing for the health and safety of our people, minimising damage and impact to the Group, and maintaining functional operations following a natural or man-made disaster, or a public health emergency.

Failure to maintain adequate governance and oversight over third-party relationships; failure of third-parties to meet their contractual, regulatory, confidentiality or other obligations; failure of third-parties to comply with the law or appropriately manage their respective operations to mitigate the Principal Risks to the Group outlined above.

Risk impact

Failure to adequately manage third-party relationships could result in business interruption and exposure to risk ranging from sub-optimal contractual terms and conditions, to severe business sanctions and/or significant reputational damage. Any of these consequences could materially and adversely affect our business operations and financial results.

Context

Third parties are critical to our business delivery and are an integral part of the solution to improve our productivity, quality, service and innovation. We rely on third-parties, including suppliers, distributors, individual contractors,

licensees, and other pharmaceutical and biotechnology collaboration partners for discovery, manufacture, and marketing of our products and important business processes.

However, these business relationships present a material risk. For example, we share critical and sensitive information such as marketing plans, clinical data, and employee data with specific third parties who are conducting the relevant outsourced business operations. Inadequate protection or misuse of this information by third parties could have significant business impact. Similarly, we use distributors and agents in a range of activities such as promotion and tendering which have inherent risks such as inappropriate promotion or corruption. Insufficient internal compliance and controls by the distributors could affect our reputation. These risks are further increased by the complexities of working with large numbers of third parties.

Table of Contents

Item 4. Information on the Company

4.A History and development of the company

The information set forth under the heading:

About GSK on the inside back cover;

Head Office and Registered Office on the outside back cover; and

Note 38 Acquisitions and disposals on pages 183 to 187

of the GSK Annual Report 2014 is incorporated herein by reference.

4.B Business overview

See Item 3D Risk factors above;

In addition, the information set forth under the headings:

Overview of 2014 on the inside front cover;

Chairman s statement on pages 2 to 3;

CEO s Statement on pages 4 to 5;

What we do on pages 6 to 7;

Our Global Marketplace on pages 8 to 10;

Our business model on page 11;

Our strategic priorities on pages 12 to 13;

How we performed on pages 14 to 15;

Risk management, on pages 16 to 17;

Deliver within Pharmaceuticals and Vaccines on pages 24 to 26, Viiv Healthcare on page 32 and Consumer Healthcare on page 34;

Pharmaceuticals R&D Approach on pages 26 to 27;

Investment in R&D on page 27;

Vaccines R&D Approach on page 28;

Late-stage pipeline on page 29;

Simplify within Pharmaceuticals and Vaccines on page 30, Viiv Healthcare on page 32 and Consumer Healthcare on page 35;

Responsible business on pages 36 to 47;

Note 6 Segment Information on pages 147 to 151;

Note 38 Acquisitions and disposals on pages 183 to 187;

Pharmaceutical products, competition and intellectual property on pages 229 to 231; and

Consumer Healthcare products and competition on page 231

of the GSK Annual Report 2014 is incorporated herein by reference.

4.C Organizational structure

The information set forth under the heading:

Note 44 Principal Group companies on pages 204 to 205

of the GSK Annual Report 2014 is incorporated herein by reference.

4.D Property, plants and equipment

The information set forth under the headings:

Note 6 Segment information on pages 147 to 151; and

Note 17 Property, plant and equipment on pages 158 to 159

of the GSK Annual Report 2014 is incorporated herein by reference.

Table of Contents

Item 4A. **Unresolved Staff Comments**

Not applicable.

Item 5. **Operating and Financial Review and Prospects**

5.A Operating results

The information set forth under the headings:

Pricing and Regulation on pages 8 to 10;

Intellectual Property and patent protection on page 10;

Grow within Pharmaceuticals and Vaccines on pages 21 to 23, Viiv Healthcare on pages 31 to 32 and Consumer Healthcare on page 34;

Group financial review on pages 48 to 60 and 62 to 70; and

Financial record Quarterly trend on pages 218 to 219

of the GSK Annual Report 2014 is incorporated herein by reference.

The following tables reconcile total results to core results. References in the GSK Annual Report 2014 to the reconciliations on page 61 of that report should be read to refer to the information in these tables.

Core results reconciliation
31 December 2014

	Core results £ m	Intangible amortisation £ m	Intangible impairment £ m	Major restructuring £ m	Legal charges £ m	Acquisition accounting and other £ m	Total results £ m
Gross profit	16,471	(503)	(78)	(204)		(3)	15,683
Operating profit	6,594	(575)	(150)	(750)	(548)	(974)	3,597
Profit before taxation	5,978	(575)	(150)	(755)	(548)	(982)	2,968
Profit after taxation	4,806	(366)	(121)	(540)	(522)	(426)	2,831

Earnings per share	95.4p	(7.6)p	(2.5)p	(11.3)p	(10.9)p	(5.8)p	57.3p
Weighted average number of shares (millions)	4,808						4,808
The following adjustments are made in arriving at core gross profit							
Cost of sales	(6,535)	(503)	(78)	(204)		(3)	(7,323)
The following adjustments are made in arriving at core operating profit							
Selling, general and administration	(7,074)			(430)	(548)	(194)	(8,246)
Research and development	(3,113)	(72)	(72)	(116)		(77)	(3,450)
Other operating income						(700)	(700)
The following adjustments are made in arriving at core profit before tax							
Net finance costs	(646)						