GLAXOSMITHKLINE PLC
Form 20-F
March 18, 2016
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As filed with the Securities and Exchange Commission on March 18, 2016

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, 2015

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
0.700% 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
5.375% Notes due 2034	London 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 **5,361,307,647**

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

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Pursuant to Rule 12b-23(a) of the Securities Exchange Act of 1934, as amended, the information for the 2015 Form 20-F of GlaxoSmithKline plc set out below is being incorporated by reference from the GSK Annual Report 2015 included as exhibit 15.2 to this Form 20-F dated and submitted on March 18, 2016 (the GSK Annual Report 2015).

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 101, Directors statement of responsibilities on page 130, Directors statement of responsibilities in relation to the company s financial statements on page 211, Share capital and control on pages 241 to 242, Financial calendar , Results announcements ; Financial reports and Annual General Meeting 2016 on page 243, Registrar on page 246, 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 247, Section 13(r) of the US Securities Exchange Act on page 249 and Glossary of terms on page 259 in each case of the GSK Annual Report 2015 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 2015 incorporated by reference herein, namely the Directors Report (for which see page 101 thereof), the Strategic Report (pages 2 to 72 thereof, portions of which are incorporated by reference as described below) and the Remuneration Report (pages 102 to 126, portions of which are incorporated by reference as described below). 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 2015 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 2015 incorporated by reference herein contain references to our website. Information on our website or any other website referenced in the GSK Annual Report 2015 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 243

of the GSK Annual Report 2015 is incorporated herein by reference.

3.B Capitalization and indebtedness

Not applicable.

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3.C Reasons for the offer and use of proceeds

Not applicable.

3.D Risk factors

Principal risks 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 must 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 likelihood of doing so successfully.

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 our significant unresolved disputes and potential litigation is set out in Note 45, Legal proceedings , on pages 206 to 210 of the GSK Annual Report 2015.

Patient safety

Risk definition

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.

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.

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Intellectual property

Risk definition

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 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.

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 significant 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 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 228 to 229 of the GSK Annual Report 2015. Legal proceedings involving patent challenges are set out in Note 45 to the financial statements, Legal proceedings on pages 206 to 210 of the GSK Annual Report 2015.

Product quality

Risk definition

Failure to comply with current Good Manufacturing Practices (cGMP) or inadequate controls and governance of quality in the supply chain covering supplier standards, manufacturing and distribution of products.

Risk impact

A failure to ensure product quality could have far reaching implications in terms of patient and consumer safety resulting in product launch delays, supply interruptions and product recalls which would have the potential to do damage to our reputation. Associated regulatory, legal, and financial consequences could materially and adversely affect our reputation and financial results.

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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, consistency of manufacturing components, compliance with GMP, accuracy of labelling, 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, with increasing scrutiny of supply continuity, a focus on improved distribution practice and the introduction of novel cell and gene based therapies. Review of inspections conducted across the industry by national regulatory authorities during 2015 highlighted an ongoing focus on data integrity, contamination prevention and the rigour of quality investigations including the robustness of decision making and the timely escalation of pertinent issues to regulatory authorities.

Financial control and reporting

Risk definition

Failure to comply with current tax law or incurring significant losses due to treasury activities; failure to report accurate financial information in compliance with accounting standards and applicable legislation; failure to maintain adequate governance and oversight over third-party relationships.

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. 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 inconsistent application of treasury policies, transactional or settlement errors, or counterparty defaults. Any changes in the substance or application of the governing tax laws, failure to comply with such tax laws or significant losses due to treasury activities could materially and adversely affect our financial results.

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

The Group is 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 new, revised or existing accounting and regulatory requirements. The Group believes that it complies with the appropriate regulatory requirements concerning our financial statements and disclosure of material information including any transactions relating to business restructuring such as acquisitions and divestitures. However, should we be subject to an investigation into potential non-compliance with accounting and disclosure requirements, this may lead to restatements of previously reported results and significant penalties.

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 reflects rates of tax in the jurisdictions in which the Group operates that are both higher and lower than the UK rate and take into account regimes that encourage innovation and investment in science by providing tax incentives which, if changed, could affect the Group s tax rate.

The tax charge included in our financial statements is our best estimate of tax liability pending audits by tax authorities. The worldwide nature of our operations and cross-border supply routes can be complex and can lead to questions on tax audit.

There continues to be a significant international focus on tax reform, including the OECD s BEPS project and European Commission initiatives such as the proposed anti-BEPS Directive and the increased use of fiscal state aid investigations. Together with domestic initiatives around the world, these may result in significant changes to established tax principals and an increase in tax authority disputes. These, regardless of their merit or outcomes, can be costly, divert management attention and may adversely impact our reputation.

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.

Third party 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.

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Anti-Bribery and Corruption (ABAC)

Risk definition

Failure to prevent GSK employees and third parties not complying with our ABAC principles and standards, as well as with all applicable legislation.

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.

The US and UK authorities are leading extra-territorial ABAC enquiries into certain of the Group s operations. These investigations are discussed further in Note 45 Legal proceedings on pages 206 to 210 of the GSK Annual Report 2015.

Commercialisation

Risk definition

Failure to execute business strategies, or manage competitive opportunities or threats effectively and in accordance with the letter and spirit of legal, industry or company requirements.

Risk impact

Failure to manage risks related to commercialisation could materially and adversely affect our ability to grow a diversified global business and deliver more products of value.

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 products and possibly suboptimal treatment of patients and consumers. Any of these consequences could materially and adversely affect the Group. Any practices that are found to be misaligned with our values could also result in reputational damage and dilute trust established with key stakeholders.

Context

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 achieve our strategic objectives.

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 ability to achieve our strategic objectives.

We are committed to the ethical and responsible commercialisation of our products 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 provide important information about our medicines.

Promotion of approved products seeks to ensure that Healthcare Professionals (HCPs) globally have access to information they need, that patients and consumers have access to the products they need and that products are prescribed, recommended or used in a manner that provides the maximum healthcare benefit to patients and consumers. We are committed to communicating information related to our approved products in a responsible, legal, and ethical manner.

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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 or recommending 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.

In 2012, we paid $3 billion (£1.9 billion) to resolve government investigations in the US focused in large part on promotional practices and in 2014 we paid RMB 3 billion (£301 million), to resolve a government investigation in China focused on offering money or property to non-government personnel in order to obtain improper commercial gains.

Research practices

Risk definition

Failure adequately to conduct ethical and sound preclinical and clinical research. In addition, failure to engage in scientific activities that are consistent with the letter and spirit of the law, industry, or the Group s requirements.

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 brought against the Group by governmental and private plaintiffs (product liability suits and claims for damages), and regulatory action such as fines, penalties or loss of product authorisation. Any of these consequences 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.

Scientific Engagement (SE) is an essential part of scientific discourse defined as the interaction and exchange of information between GSK and external communities in order to advance scientific and medical understanding, including the appropriate development and use of our products. Such non-promotional engagement with external stakeholder groups is vital to GSK s mission and necessary for scientific and medical advance.

The scope of SE activities includes: advisory boards; scientific consultancies; pre-planned informal discussions with HCPs; sharing medical information; publications (including abstracts to congresses); scientific interactions with payers, patients, governments and the media; and support for Independent Medical Education. Non-independent educational activities are covered by Commercial Practices (CP).

SE activities are essential but present legal, regulatory, and reputational risk if the sharing of data, invited media coverage or payments for service providers has, or is perceived to have, inappropriate promotional intent. The risks are particularly high where HCP engagement and associated Financial and/or Transfer of Value disclosures are required by GSK.

Environment, health and safety and sustainability (EHSS)

Risk definition

Failure to manage EHSS risks in line with our objectives and policies and with relevant laws and regulations.

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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 on pages 206 to 210 of the GSK Annual report 2015, for a discussion of the environmental related proceedings in which we are involved. We routinely accrue amounts related to our liabilities for such matters.

Information protection

Risk definition

Failure to protect and maintain access to critical or sensitive computer systems or information.

Risk impact

Failure to adequately protect critical and sensitive systems and information may result in loss of commercial or strategic advantage, damage to our reputation, litigation, or other business disruption including regulatory sanction, 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.

Several GSK employees were indicted for theft of GSK research information. While the charges against the individuals are concerning, based on what we know, we do not believe this breach has had any material impact on the company s R&D activity or ongoing business. GSK is conducting a full internal review into what occurred, and planning to continue to enhance the multiple layers of data protection that we already have in place.

Crisis and continuity management

Risk definition

Failure to deliver a continuous supply of compliant finished product; inability to recover and sustain critical operations, including key supply chains, following a disruption, or to respond to a crisis incident, in a timely manner.

Risk impact

We recognise that failure to supply of our products can adversely impact consumers and patients who rely on them. A material interruption of supply or exclusion from healthcare programmes could expose us to litigation or regulatory action, incurring of fines or disgorgement and materially and adversely affect the Group s financial results. The Group s international operations, and those of its partners, maintain a vast global footprint also expose 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). It is important for GSK to have robust crisis management and recovery plans in place to manage such events.

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.

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 organisations and clinical research organisations to support development of key products, are important to ensure continuous operation

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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 fulfil 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.

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.

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 185 to 189

of the GSK Annual Report 2015 is incorporated herein by reference.

4.B Business overview

See Item 3D Risk factors above;

In addition, the information set forth under the headings:

Our investor proposition on pages 2 to 3;

Our business on pages 4 to 5;

Chairman s statement on page 6;

CEO s statement on page 7 (excluding (i) the graphic under the heading 2015 highlights and (ii) the pro-forma figures in the parentheticals in the first and the fourth paragraphs under the subheading Trading performance);

Our global marketplace on pages 8 to 10;

Our business model on page 11;

Our strategic priorities on pages 12 to 13;

Pharmaceuticals on pages 20 to 25 (excluding (i) the graphic under the heading 2015 performance summary on page 20 and (ii) the second sentence in the second paragraph under the subheading Grow on page 22);

Vaccines on pages 28 to 31 (excluding (i) the graphic under the heading 2015 performance summary on page 28; (ii) the second, third and fifth sentence in the first paragraph under the subheading Grow on page 28; (iii) the graphic under the heading Our strategy in action on page 28; and (iv) the third sentence in the first paragraph under the subheading Simplify on page 31);

Consumer Healthcare on pages 34 to 37 (excluding (i) the graphic under the heading 2015 performance summary on page 34; (ii) the first sentence in the first paragraph and the second sentence in the second paragraph under the subheading Grow on page 36; and (iii) the second sentence in the second paragraph under the subheading Simplify on page 37);

Responsible business on pages 40 to 49;

Note 6 Segment information on pages 149 to 152;

Note 38 Acquisitions and disposals on pages 185 to 189;

Pharmaceutical products, competition and intellectual property on pages 228 to 229;

Vaccines products, competition and intellectual property on page 229; and

Consumer Healthcare products and competition on page 230

of the GSK Annual Report 2015 is incorporated herein by reference.

4.C Organizational structure

The information set forth under the heading:

Note 44 Principal Group companies on page 205; and

Group Companies on pages 250 to 258

of the GSK Annual Report 2015 is incorporated herein by reference.

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4.D Property, plant and equipment
The information set forth under the headings:

Property, plant and equipment within Group financial review on page 66;

Note 6 Segment information on pages 149 to 152; and

Note 17 Property, plant and equipment on pages 161 to 162
of the GSK Annual Report 2015 is incorporated herein by reference.

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 market access on pages 8 and 10;

Regulatory environment on page 10;

Intellectual Property and patent protection developments on page 10;

Grow within Pharmaceuticals on page 22 (excluding the second sentence in the second paragraph under the subheading Grow);

Grow within Vaccines on page 28 (excluding (i) the graphic under the heading 2015 performance summary , (ii) the second, third and fifth sentences in the first paragraph under the subheading Grow and (iii) the graphic under the heading Our strategy in action);

Grow within Consumer Healthcare on page 36 (excluding the first sentence in the first paragraph and the second sentence in the second paragraph under the subheading Grow);

Cash generation and conversion on page 65;

Financial position and resources on pages 66 to 69;

Non-controlling interests in Viiv Healthcare on page 70;

Critical accounting policies on pages 70 to 71;

Treasury policies on page 72; and

Strategic report on page 72

of the GSK Annual Report 2015 is incorporated herein by reference.

The following tables reconcile total results to core results. References in the GSK Annual Report 2015 to the reconciliations on page 62 of that report should be read to refer to the information in these tables.

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Core results reconciliation	**31 December 2015**							
	Total results £m	Intangible asset amortisation £m	Intangible asset impairment £m	Major restructuring £m	Legal charges £m	Acquisition accounting £m	Disposals and other £m	Core results £m
Gross profit	15,070	522	147	563		89	12	16,403
Operating profit	10,322	563	206	1,891	221	2,238	(9,712)	5,729
Profit before taxation	10,526	563	206	1,896	221	2,238	(10,559)	5,091
Profit after taxation	8,372	402	156	1,455	200	1,886	(8,373)	4,098
Earnings per share	174.3p	8.3p	3.2p	30.1p	4.1p	28.8p	(173.1)p	75.7p
Weighted average number of shares (millions)	4,831							4,831
The following adjustments are made in arriving at core gross profit								
Cost of sales	(8,853)	522	147	563		89	12	(7,520)
The following adjustments are made in arriving at core operating profit								
Selling, general and administration	(9,232)		7	1,009	221	88		