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 risks below are those that we believe could cause our actual results to differ materially from expected and historical results. During 2018 we have evolved the cycle of management of these risks which helps us Identify, manage and report on our most important risks in a proportionate and consistent way.

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

Also, during 2018 we have improved consistency of risk management across the organisation through evolution of our enterprise risk management and reporting cycle.

As rules and regulations change, and governmental interpretation 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 regulations could materially and adversely affect our financial results.

Similarly, our global 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 215 to 218 of the GSK Annual Report 2018.

Patient safety

Risk definition

Failure to appropriately collect, review, follow up, or report human safety information (HSI), including adverse events from all potential sources, and to act on any relevant findings in a timely manner.

Risk impact

The risk impact has the potential 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 about the safety of our products 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. Constant vigilance and flexibility is required in order to respond to a varied regulatory environment which continues to evolve and diverge globally.

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 take 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.

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. This would have the potential to do damage to our reputation, as well as result in other regulatory, legal and financial consequences.

Context

Patients, consumers and HCPs trust the quality of our products. 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 and new legislation are introduced. Critically, we are addressing the impact of Brexit on our supply chain management and quality oversight between the UK and the EU and are developing and deploying appropriate contingency plans to avoid interruption of supply to patients.

Financial controls and reporting

Risk definition

Failure to comply with current tax laws or incurring significant losses due to treasury activities; failure to report accurate financial information 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. 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 debt funding, 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.

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. These transactions involve market volatility and counterparty risk.

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 takes into account regimes that encourage innovation and investment in science by providing tax incentives which, if changed, could affect the Group’s tax rate. In addition, the worldwide nature of our operations means that our intellectual property, R&D and manufacturing operations are centered in a number of key locations. A consequence of this is that our cross-border supply routes, necessary to ensure supplies of medicines into numerous end markets, can be complex and result in conflicting claims from tax authorities as to the profits to be taxed in individual countries. Tax legislation itself is also complex and differs across the countries in which we operate. As such, tax risk can also arise due to differences in the interpretation of such legislation. The tax charge included in our financial statements is our best estimate of tax liability pending audits by tax authorities.

We expect there to be continued focus on tax reform in 2019 and future years driven by initiatives of the Organisation for Economic Cooperation & Development to address the taxation of the digital economy and European Commission initiatives including the use of fiscal state aid investigations. Together with domestic initiatives around the world, these may result in significant changes to established tax principles 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 and relationship with key stakeholders.

Anti-bribery and corruption (ABAC)

Risk definition

Failure of GSK employees, consultants and third parties to comply with our Anti-bribery & corruption (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 and may compromise the Group’s ability to supply its products under certain government contracts. In addition to legal and financial penalties, a failure to prevent bribery through complying with ABAC legislation and regulations could have substantial implications for the reputation of the company, the credibility of senior leaders, and an erosion of investor confidence in our governance and risk management.

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 by its very nature maintains relationships with government bodies, is highly competitive and subject to regulation. This increases the instances where we are exposed to bribery and corruption risk.

The Group has been subject to a number of ABAC inquiries. We reached a resolution with the US authorities in 2016 regarding their ABAC inquiry, following which we were subject to a self-monitoring arrangement. The self-monitorship concluded in September 2018. Government investigations regarding our China and other business operations are ongoing. These investigations are discussed further in Note 45, ‘Legal proceedings’ on pages 215 to 218 of the GSK Annual Report 2018.

Commercial practices

Risk definition

Failure to engage in commercial activities that are consistent with the letter and spirit of the law, 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 manage risks related to commercial practices could materially and adversely affect our ability to grow a diversified global business and deliver more products of value for patients and consumers. 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 which could result in government sanctions, and criminal and/or financial penalties. Failure to provide accurate and complete information related to our products may result in incomplete awareness of the risk/benefit profile of our products and possibly suboptimal treatment of patients and consumers.

Any practices that are found to be misaligned with our values could also result in reputational harm and dilute trust established with external 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 that reflect insights which help ensure those products address the needs of patients/consumers, HCPs, and payers are critical to achieve our strategic objectives.

As other pharmaceutical, vaccine and consumer companies, we face downward price pressure in major markets, declining emerging market growth, and negative foreign exchange impact.

Developing new Pharmaceutical, Vaccine and Consumer Healthcare products is a costly, lengthy and an uncertain process. A product candidate may fail at any stage, including after significant 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 HCPs globally have access to information they need, that patients and consumers have access to the information and 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.

Privacy

Risk definition

The failure to collect, secure, use and destroy personal information (PI) in accordance with applicable data privacy laws.

Risk impact

Non-compliance can lead to harm to individuals (e.g. financial loss, distress, prejudice) and GSK (e.g. fines, management time, operational inefficiency, out of pocket costs, and reputational damage). It can also damage trust between GSK and individuals, communities, business partners and government authorities.

The General Data Protection Regulation (GDPR) increased the enforcement powers of EU supervisory authorities, including by allowing them to impose fines of up to 4% of global revenue, and to require the suspension of processing PI in certain circumstances. GDPR also gives individuals the right to bring collective legal actions against GSK for failure to comply with data privacy laws.

Context

Data Privacy laws are diverse, with limited harmonisation, despite Europe's adoption of GDPR. In many countries in which GSK operates, local data privacy laws govern how GSK can collect and use PI. It is challenging for multi-nationals to standardise their approach to compliance with data privacy laws due to the high-level of local variation. Governments are enforcing compliance with data privacy laws more rigorously. There is an increasing focus on the ethical use of PI, over and above compliance with data privacy laws, and individuals are increasingly aware of their rights under data privacy laws.

Research practices

Risk definition

Failure to adequately 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, and failure to secure adequate patent protection for GSK's products.

Risk impact

The impacts of the risk include harm to human subjects, 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), loss of revenue due to inadequate patent protection or inability to supply GSK products, and regulatory action such as fines, penalties, or loss of product authorisation. Any of these consequences could materially and adversely affect our financial results and cause loss of trust from our customers and patients.

Context

Research relating to animals can raise ethical concerns. While we attempt to address this proactively, 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 studied in humans. Animal research can provide critical information about the causes of diseases and how they develop. Nonetheless, we are continually seeking ways in which we can minimise our use of animals in research, whilst complying with regulatory requirements.

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, 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 form the content of regulatory submissions, publications and patent filings. Poor data integrity can compromise our research efforts and negatively impact company reputation.

There are innate complexities and interdependencies required for regulatory filings, particularly given our global research and development footprint. Continually changing and increasingly stringent submission requirements continue to increase the complexity of worldwide product registration.

Scientific engagement (SE), defined as the interaction and exchange of information between GSK and external communities to advance scientific and medical understanding, including the appropriate development and use of our products, is an essential part of scientific discourse. Such non-promotional engagement with external stakeholder groups is vital to GSK's mission and necessary for scientific and medical advance. SE activities are essential but present legal, regulatory, and reputational risk if the sharing of data, invited media coverage or payments to HCPs have, or are perceived to have, promotional intent.

A wide variety of biological materials are used by GSK in discovery, research and development phases. Through the Convention on Biological Diversity (CBD) and the Nagoya Protocol, the international community has established a global framework regulating access to, and use of, genetic resources of non-human origin in Research and Development (R&D). We support the principles of access and benefit sharing to genetic resources as outlined in the CBD and the Nagoya Protocol, recognising the importance of appropriate, effective and proportionate implementation measures at national and regional levels.

Patent rights play an important role in providing GSK with a competitive advantage in the market. Any loss of patent protection in a market for GSK's products developed through our R&D, including reducing the availability or scope of patent rights, could materially and adversely affect our financial results in that market. Absence of adequate patent or data exclusivity protection, which could lead to, for example, competition from manufacturers of generic pharmaceutical products, could limit the opportunity to rely on such markets for future sales growth for our products, which could also materially and adversely impact our financial results. Following expiration of certain intellectual property rights, a generic manufacturer may lawfully produce a generic version of a product. Introduction of generic products typically leads to a rapid and dramatic loss of sales and reduces our revenues and margins for our proprietary products.

Third party oversight risk (TPO)

Risk definition

Failure to maintain adequate governance and oversight over third party relationships and failure of third parties to meet their contractual, regulatory, confidentiality or other obligations.

Risk impact

Failure to adequately manage third party relationships could result in business disruption and exposure to risks ranging from sub-optimal contractual terms and conditions, to severe business and legal 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 meeting our business objectives. We rely on third parties, including suppliers, advisors, distributors, individual contractors, licensees, and other pharmaceutical and biotechnology collaboration partners for discovery, manufacture, and marketing of our products and for supporting other important business processes.

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 activities. 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 across a diverse geographical spread.

Environment, health & safety and sustainability (EHS&S)

Risk definition

Failure to manage environment, health & safety and sustainability (EHS&S) risks in line with our objectives and policies and with relevant laws and regulations.

Risk impact

Failure to manage EHS&S 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, which could materially and adversely affect our financial results.

Context

We are 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 in the US. 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.

Information security

Risk definition

The risk to GSK business activities if information becomes disclosed to those not authorised to see it, or if information or systems fail to be available or are corrupted, typically because of cybersecurity threats, although accident or malicious insider-action may be contributory causes.

Risk impact

Failure to adequately protect critical and sensitive systems and information may result in loss of commercial or strategic advantage and could materially affect our ongoing business operations, such as scientific research, clinical trials and manufacturing and supply chain activities.

Context

We rely on critical and sensitive systems and data, such as corporate strategic plans, intellectual property, manufacturing systems and trade secrets. There is the potential that our computer systems or information may be exposed to misuse or unauthorised disclosure.

We believe that the cyber security incidents that we have experienced to date have not resulted in significant disruptions to our operations and have not had a significant adverse effect on our results of operations, or on third parties. However, as the threats evolve we cannot provide assurance that our significant efforts in protecting and monitoring our systems and information will always be successful in preventing compromise or disruption in future. They increasingly involve highly-resourced threat actors such as nation-states and organised criminals. Combined with the size and complexity of our IT systems and those of our supply chain partners (including outsourced operations), this means that our systems and information have been, and are expected to continue to be, the subject of cyber-attacks of various types.

Supply continuity

Risk definition

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

Risk impact

We recognise that failure to supply 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 and financial penalties that could adversely affect the Group's financial results. The Group's international operations, and those of its partners, expose our workforce, facilities, operations and information technology to potential disruption from natural events (e.g. storm, earthquake), man-made events (e.g. civil unrest, terrorism), and global emergencies (e.g. Ebola outbreak, flu pandemic). It is important that we 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 license 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.

We rely on materials and services provided by third party suppliers to make our products, including active pharmaceutical ingredients (API), antigens, intermediates, commodities, and components for the manufacture and packaging of Pharmaceutical, Vaccine and Consumer Healthcare products. Some of the third party services procured, such as services provided by contract manufacturing and clinical research organisations to support development of key products, are important to ensure continuous operation of our business.

Although we undertake risk mitigation we recognise that certain events could nevertheless still result in delays or service interruptions. We use effective crisis management and business continuity planning to provide for the health and safety of our people and to minimise impact to us, by maintaining functional operations following a natural or man-made disaster, or a public health emergency.

Risks associated with the Consumer Healthcare Joint Venture with Pfizer

Completion of the transaction with Pfizer is subject to the satisfaction (or waiver, where applicable) of a number of conditions which, if not satisfied, may result in the transaction not proceeding and, in certain circumstances, could also result in the payment by GSK of a break fee

Completion of the transaction between GSK and Pfizer to form the Consumer Healthcare Joint Venture (the "Transaction") is subject to the satisfaction (or waiver, where applicable) of a number of conditions on or before September 30, 2019 (which date may be extended by either party to December 31, 2019 or March 31, 2020 in the case of the conditions relating to the receipt of antitrust clearances), including:

- the approval of the resolution in respect of the Transaction by GSK's shareholders at the General Meeting of shareholders;
- the receipt of various antitrust clearances in respect of the Transaction, including merger clearances by the EU Commission, expiry of any applicable waiting periods under the HSR Act and receipt of various other antitrust approvals;
- there being no governmental orders restraining or otherwise prohibiting the Transaction;
- the other party's representations and warranties generally being true and correct as at completion of the Transaction, except to the extent that any failure to be true and correct (individually or in the aggregate) would not have a material adverse effect in relation to that party's respective contributed business; and
- each of GSK and Pfizer having performed and complied in all material respects with its respective pre-closing covenants.

There is no guarantee that these (or any other) conditions will be satisfied (or waived, if applicable). If any of the conditions are not satisfied (or waived, if applicable), the Transaction may not complete. If the Transaction fails to complete, the anticipated benefits of the Transaction will not be achieved and GSK would nonetheless have incurred costs in connection with the Transaction. In certain circumstances where the condition relating to the approval by GSK's shareholders of the shareholders' resolution in respect of the Transaction is not satisfied, GSK may also be required to pay a break fee of $900 million to Pfizer by way of compensation.

The terms on which antitrust and regulatory approvals are provided may jeopardize or delay the Transaction, result in additional expenditure and/or reduce the anticipated benefits of the Transaction

As a condition to their clearance of the Transaction, antitrust and regulatory authorities may require the modification of the terms of the Transaction or divestitures of parts of the GSK consumer healthcare business and/or the Pfizer consumer healthcare business or may otherwise place restrictions on the conduct of the business of the GSK Group following the acquisition of the Pfizer consumer healthcare business (the "Enlarged Group"). In addition, GSK may give undertakings,

which may include proposing divestments or excluding certain assets from the Transaction, in order to obtain such clearances. Any such modifications, divestments or restrictions could jeopardise or delay completion of the Transaction, impose significant additional costs on the Enlarged Group and/or may reduce the anticipated benefits of the Transaction, any of which could materially and adversely affect the financial results of the Enlarged Group.

The outcome of the various antitrust and regulatory clearance applications is not yet known and is not within the control of GSK or Pfizer. As a result, there can be no certainty or assurance as to the outcome of such applications or that any such applications will be successful. In the event that antitrust and regulatory approvals are not received in each jurisdiction in which they are required, the Transaction may not be consummated either in that specific jurisdiction or, in certain circumstances, at all.

In addition, GSK and Pfizer are both obliged to take all actions and do all things necessary under applicable antitrust laws to consummate the Transaction. Without limiting the generality of this obligation, there is no limit on the number or value of any divestitures, undertakings or commitments that GSK may be required under the Stock and Asset Purchase Agreement with Pfizer to give in order to ensure that all antitrust and regulatory approvals required in connection with the Transaction are obtained. Any such divestitures, undertakings or commitments could reduce the anticipated benefits of the Transaction, including the realization of anticipated synergies, and could materially and adversely affect the results and operations of the Enlarged Group.

The Enlarged Group may experience difficulties in integrating the Pfizer consumer healthcare business with the GSK consumer healthcare business

The future prospects of the Enlarged Group will, in part, be dependent upon the Enlarged Group's ability to integrate the Pfizer consumer healthcare business with the existing GSK consumer healthcare business, and the ability of the Enlarged Group to realize the anticipated benefits and cost savings from combining the respective businesses. Some of the potential challenges relating to integration may not become known until after completion of the Transaction.

The key potential difficulties in integrating the businesses include the following:

- the complexity of transferring employees and assets (including intellectual property, third party contracts, real estate and marketing authorizations and other licenses/permits) and consolidating operations, infrastructure, procedures, systems, facilities, services and policies across many different countries, jurisdictions, regulatory systems and business cultures;
- maintaining employee engagement and retaining and incentivizing key employees;
- the diversion of management time and resources away from the day-to-day operations of the Group;
- ensuring readiness upon completion of the Transaction and limiting disruption to the ongoing businesses of the Enlarged Group, including minimizing the risk of supply chain interruptions and ensuring that necessary transitional arrangements between Pfizer and the Enlarged Group function successfully;
- replacing and/or integrating IT systems used by the Pfizer consumer healthcare business with those used by the GSK consumer healthcare business and transferring relevant data from Pfizer IT systems to GSK IT systems;
- technical transfer of manufacturing and other processes and services, upon expiry of transitional manufacturing and services arrangements and/or in-sourcing of third party supply contracts; and
- maintaining business continuity throughout integration.

Difficulties experienced in the integration process could potentially lead to the interruption of operations of the businesses, or a loss of customers, suppliers or key personnel, which could have a material adverse effect on the business, results of operations or financial condition of the Enlarged Group.

Transaction-related costs may exceed GSK's expectations

GSK expects to incur costs in relation to the Transaction, including integration and post-completion costs in order to implement the Transaction successfully and deliver anticipated costs savings. The actual costs may exceed those estimated and there may be additional and unforeseen expenses incurred in connection with the Transaction. In addition, GSK has incurred and will incur legal, accounting and transaction fees and other costs relating to the Transaction, a material part of which are payable whether or not the Transaction completes. Such costs could materially and adversely affect the realization of synergies and the results of operations of the Group or the Enlarged Group.

The Enlarged Group may fail to realize, or it may take longer than expected to realize, the anticipated benefits of the Transaction

The expected benefits of the Transaction, including any identified synergies, may not be achieved, or may take longer than expected to realize, and other assumptions upon which the terms of the Transaction have been determined may prove to be incorrect. To the extent that GSK incurs higher integration costs, achieves lower margin benefits or fewer cost savings than expected, the results of operations and financial condition of the Enlarged Group may suffer, which may materially and adversely affect GSK's share price.

The Stock and Asset Purchase Agreement with Pfizer contains certain representations, warranties and indemnities, which could require GSK or GlaxoSmithKline Consumer Healthcare Holdings Limited ("GSK Consumer Healthcare") to make payments to Pfizer

The Stock and Asset Purchase Agreement with Pfizer contains certain representations, warranties and indemnities given by GSK and GSK Consumer Healthcare in favor of Pfizer. Any payment required under those representations, warranties and indemnities may have a material and adverse effect on the cash flow and financial condition of the Enlarged Group.

The consumer healthcare joint venture with Pfizer and the Enlarged Group may not have full recourse to Pfizer under the Stock and Asset Purchase Agreement

Under the terms of the Stock and Asset Purchase Agreement, Pfizer provides GSK Consumer Healthcare and GSK with certain representations, warranties and indemnities. However, these representations, warranties and indemnities may not cover all potential liabilities associated with the Pfizer consumer healthcare business, and they are in certain circumstances limited in their scope, duration and/or the amount which may be claimed under them. Accordingly, GSK Consumer Healthcare and GSK may not have recourse against Pfizer, or may not recover in full from Pfizer, for losses which it may suffer in respect of a breach of those warranties, or in respect of the subject matter of any of the indemnities, or otherwise in respect of the consumer healthcare joint venture. This could materially and adversely affect the operations and financial results of the consumer healthcare joint venture and, following completion of the Transaction, the Enlarged Group.

Events or developments may occur which have an adverse effect on the businesses that are the subject of the Transaction but do not entitle GSK to terminate the Transaction

Pursuant to the Stock and Asset Purchase Agreement, GSK will only be entitled to terminate the Transaction: (i) if agreed between the parties; (ii) if completion of the Transaction has not occurred by September 30, 2019 (which date may be extended by either party to December 31, 2019 or March 31, 2020 if the Transaction has not completed as a result of a failure to satisfy (or waive, as applicable) any of the conditions relating to the receipt of antitrust clearances); (iii) if Pfizer fails to perform its obligations at completion of the Transaction; (iv) if any breach of Pfizer's representations and warranties as at completion of the Transaction constitutes a material adverse effect in relation to the Pfizer consumer healthcare business; (v) Pfizer has materially breached its covenants and agreements to be performed or complied with prior to completion of the Transaction; (vi) there being a governmental order permanently prohibiting the Transaction; or (vii) if GSK's shareholders do not approve the shareholders' resolution in relation to the Transaction at the General Meeting of shareholders.

During the period prior to completion of the Transaction, events or developments may occur which have an adverse effect on the Pfizer consumer healthcare business but do not enable GSK to terminate the Transaction under the terms of the Stock and Asset Purchase Agreement. GSK would then be required to proceed to completion of the Transaction notwithstanding the adverse events or developments, and this could have a material and adverse effect on the business, financial condition and results of GSK.

Failure to obtain third party consents from contractual counterparties of the Pfizer consumer healthcare business may reduce the anticipated benefits of the Transaction

The Pfizer group is party to a number of contracts relating to the Pfizer consumer healthcare business with third parties in respect of which it is intended that either the relevant contracting entity within the Pfizer group will be transferred to the consumer healthcare joint venture or the contract will be assigned to the consumer healthcare joint venture. Certain of those contracts may provide the counterparty with a right to terminate as a result of (i) the change of control of, or assignment by, the Pfizer contracting party; and/or (ii) breach of applicable non-compete restrictions as a result of the contract being held within the Enlarged Group. If such contracts are terminated or the counterparties do not grant consents/waivers on favourable terms, this may reduce the anticipated benefits of the Transaction and could have a material adverse effect on the Enlarged Group's business, financial condition and/or results of operations.

Risks of executing the Transaction could cause the market price of GSK shares to decline

The market price of GSK's shares may decline as a result of the Transaction, among other reasons, if:

- the integration of the Pfizer consumer healthcare business into the Group is delayed or unsuccessful;

- GSK does not achieve the anticipated benefits of the Transaction as rapidly, or to the extent anticipated by GSK's management, analysts or investors, or at all;
- the effect of the Transaction on GSK's financial results is not consistent with the expectations of analysts or investors; or
- GSK's shareholders sell a significant number of shares following completion of the Transaction.

The successful completion of a separation of the consumer healthcare joint venture initiated by GSK may be dependent on a number of factors that are outside GSK's control, including favorable conditions in public equity markets and public or private debt markets and changes in applicable law and regulation

GSK's ability to exit the consumer healthcare joint venture through a listing and admission to trading of shares of GSK Consumer Healthcare on the London Stock Exchange, the Nasdaq Stock Market or the New York Stock Exchange (the "Separation") initiated by GSK may be dependent on a number of factors such as (i) the condition of public or private debt markets being such that the consumer healthcare joint venture is able to raise, on terms acceptable to the Group, sufficient levels of debt finance to undertake a pre-separation recapitalization and distribution of the proceeds to GSK and Pfizer and (ii) the condition of public equity markets being such as to enable a successful sale or demerger of shares in the consumer healthcare joint venture. Conditions in public equity markets and public or private debt markets are not within GSK's control and disruption in those markets may impede GSK's ability to exit the consumer healthcare joint venture at the desired time or in the desired way.

In addition, GSK's ability to implement a successful Separation initiated by GSK, including by way of a demerger of its equity stake and a listing of the consumer healthcare joint venture on the London Stock Exchange, the Nasdaq Stock Market or the New York Stock Exchange, may be impeded or prevented by any change of law, regulation or the rules of any authority to which GSK is subject (including, for example, any rules or guidance issued by the U.K. Financial Conduct Authority or H. M. Revenue & Customs) or any change to the way in which applicable law and regulation is interpreted and applied by the relevant authorities. Such changes are outside the control of GSK and there can be no guarantee that GSK's preferred strategy in relation to the Separation will be capable of being implemented.

If GSK is not able to execute a successful Separation, including by undertaking a pre-separation recapitalization of the consumer healthcare joint venture and completing a demerger of its equity stake, at a time and on terms acceptable to it, the Group may not be able to implement its preferred strategy, including in relation to its pharmaceuticals and vaccines business, the reduction of leverage associated with those businesses, and the support for those businesses' ongoing investment requirements (especially the Group's R&D pipeline). This may have a material and adverse effect on the business, financial condition, results and operations of the Enlarged Group.

The expected benefits of a successful completion of a Separation initiated by GSK of the consumer healthcare joint venture from the Group may not be realized and such a Separation may be detrimental to the consumer healthcare joint venture and/or the Group

Following a successful Separation, there can be no guarantee that the expected benefits of such a Separation will be realized. In particular, if such a Separation does proceed, both the consumer healthcare joint venture and the Group (excluding the consumer healthcare business) will form smaller, less diversified groups. As a result, each separate group may be more exposed to cyclical, sector-specific or other risks than the Group and, following completion of the Transaction, the Enlarged Group are currently. In addition, consistent with their smaller sizes, each separate group may not be able to obtain future debt or equity financing or put in place other contractual arrangements on terms as favorable as the Group and, following completion of the Transaction, the Enlarged Group are currently able to achieve. Were any of these risks to be realized following a Separation, this may have a material and adverse effect on the business, financial condition, results and operations of the consumer healthcare joint venture and/or the Group (excluding the consumer healthcare business).

The completion of a Separation initiated by Pfizer, causing the consumer healthcare joint venture to become a listed, publicly traded company, would reduce GSK's control over the consumer healthcare joint venture

Under the terms of the Shareholders' Agreement between GSK and Pfizer in relation to the consumer healthcare joint venture, in the event that GSK has not exercised its exit rights in respect of the consumer healthcare joint venture within five years following completion of the Transaction, Pfizer will be entitled to initiate a Separation from that point in time. While GSK would not be required to sell or demerge any of its shares in the consumer healthcare joint venture as part of such a Separation initiated by Pfizer and could therefore retain its proportionate equity stake, GSK's rights to appoint directors to the board of directors of the joint venture and other control rights would be reduced to a customary level for a company listed on the same exchange as the primary listing of the consumer