3.D **Risk Factors**

Principal risks and uncertainties

We outline below the principal risks and uncertainties relevant to GSK's business, financial condition and operations that may affect our performance and ability to achieve our objectives. These are the risks that we believe could cause our actual results to differ materially from expected and historical results.

In 2020 Board oversight was extended beyond the Audit & Risk Committee, to include more involvement from the Corporate Responsibility Committee and Science Committee. These committees considered GSK's risks and the strategies used to address them. In doing so they drew on annual business unit risk and assurance update reports, strategy papers for our most significant risks, and the Corporate Executive Team's (CET's) annual risk review.

During the year we further developed our risk management framework, moving from annual to quarterly upwards reporting for most of our principal risks. This has enabled the Risk Oversight and Compliance Council to oversee risk in a more dynamic way. We continued to evolve how we report new and emerging risks and external environmental insights. We also made reporting more data driven, with key risk indicators enabling more agile risk management strategies. In addition, risks relating to COVID-19 were incorporated within our most significant risks, to complement the pandemic risks identified and managed by the Global Issues Management Team and reported to the CET.

We are required to comply with a broad range of laws and regulations which apply to the research and development, manufacturing, testing, approval, distribution, sales and marketing of pharmaceutical, vaccine and consumer healthcare products. These affect the cost of product development, the time required to reach the market and the likelihood of doing so successfully on an uninterrupted basis.

As rules and regulations change, government interpretation evolves, and our business activities develop, the nature of a particular risk may also alter. Changes to certain regulatory regimes may be substantial. Any alteration in, and failure to comply with, applicable laws 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 unfavorable outcomes and increases in related costs such as insurance premiums, could also materially and adversely affect our financial results.

More detail on the status and various uncertainties in our significant unresolved disputes and potential litigation is set out in Note 46 'Legal proceedings' on pages 234 to 237 of the GSK Annual Report 2020, which is incorporated by reference herein.

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

Our ability to effectively collect, manage and analyze safety information associated with our products enables us to conduct robust safety signal detection activities. This, in turn, ensures we make decisions based on the most up-to-date risk/benefit profile of our products and take all appropriate measures to safeguard patients and consumers. If we do not effectively manage risks to our patient safety activities, the most serious repercussion could be harm to patients. This could also lead to reputational damage, product-related litigation, governmental investigation and regulatory action, including fines, penalties and even the loss of product marketing authorization.

Context

Our license to operate depends on our compliance with global pharmacovigilance requirements. We are fully accountable for safeguarding patients and complying with global regulations. However, we augment our pharmacovigilance capabilities by using third parties, and continue to seek innovative solutions (e.g., automation and machine learning) for improved patient safety management through more efficient, reliable and accurate data collection and interrogation.

We collect information on the safety and efficacy of our products in humans during clinical development and gain more comprehensive information on real-world use once our products are on the market. Safety information is not only obtained by our own ongoing safety surveillance activities; external parties also analyze publicly-available clinical trial results or other data. The variety of sources and the increasing volume of safety data in the setting of variable and complex global regulations present new and evolving challenges to how we conduct pharmacovigilance. For example, we must collect sensitive health information to develop robust product safety profiles while ensuring adherence to increasingly stringent global privacy regulations and remaining vigilant to the threat of cyberattacks.

As a result of the COVID-19 pandemic, GSK's Safety organization and our third parties quickly and effectively adopted new ways of working which did not impact patient safety. However, the urgent need for effective treatment and prevention of COVID-19, and the political discourse around developing such treatment and prevention, increased regulatory, governmental and public scrutiny on how our industry ensures, through development and regulatory measures, the safety and efficacy of medicines and vaccines. This environment could undermine regulatory, governmental and public trust in medicines for treating COVID-19. This may, in turn, negatively influence healthcare decisions for other diseases, leading to reputational damage or product liability lawsuits.

Product quality

Risk definition

Failure by GSK, its contractors or suppliers to ensure:

- Appropriate controls and governance of quality in product development;
- Compliance with good manufacturing practice or good distribution practice regulations in commercial or clinical trials manufacture and distribution activities;
- Compliance with the terms of GSK product licenses and supporting regulatory activities.

Risk impact

A failure to ensure product quality could have far reaching implications in patient and consumer safety, product launch delays, drug shortages and product recalls, as well as having regulatory, legal and financial consequences. These could materially and adversely affect GSK's reputation and financial results.

Context

The external environment for product quality remains challenging.

The European Medicines Agency (EMA) is about to implement two new sets of requirements. In May 2021, EMA regulations covering the licensing of medical devices will become effective. The new Annex 1 Guidance for the Manufacture of Sterile Medicinal Products is also due for release. GSK is preparing to implement both sets of requirements.

We are reviewing the manufacturing processes for all products to identify the risks for the presence of nitrosamine impurities, to comply with updated regulatory requirements. This work will continue through 2021. Where necessary we will mitigate any identified risks.

GSK is increasingly using new technology to enhance the manufacture and testing of our products, for example, we are continuing to deploy new electronic documentation systems and advanced laboratory information management tools. The threat of cyberattacks remains a key risk to the integrity of product quality data and its audit trail.

Significant changes are taking place in GSK as we implement our new organizational alignments and strategy. These changes are assessed by our quality organizations to make sure our quality procedures and governance can facilitate the strategy, while also ensuring that no unintended consequences increase our product quality risk.

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 GSK to litigation and regulatory action and could materially and adversely affect our financial results. In the current global pandemic, there can be significant changes at short notice. Failure to comply with changes in the substance or application of the laws governing transfer pricing, dividends, tax credits and intellectual property could also materially and adversely affect our financial results.

Inconsistent application of treasury policies, transactional or settlement errors, or counterparty defaults could lead to significant losses.

Context

We are required by the laws of various jurisdictions to publicly disclose our financial results and events that could materially affect the Group's financial results. Regulators routinely review the financial statements of listed companies for compliance with new, revised or existing accounting and regulatory requirements. We believe that we comply with the appropriate regulatory requirements concerning our financial statements and the 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 could lead to restatements of previously-reported results and significant penalties.

Our Treasury group deals daily in high value transactions, mostly foreign exchange and cash management transactions. These transactions involve market volatility and counterparty risk.

The Group's effective tax rate reflects the locations of our activities and the value they generate, which determine the jurisdictions in which profits arise and the applicable tax rates. These may be higher or lower than the UK statutory rate and may reflect regimes that encourage innovation and investment in R&D by providing tax incentives which, if changed, could affect GSK's tax rate. In addition, the worldwide nature of our operations means that our cross-border supply routes, necessary to ensure supplies of medicines into numerous countries, can result in conflicting claims from tax authorities as to the profits to be taxed in individual countries. This can lead to double taxation, with profits taxed in more than one country. The complexity of tax regulations also means that we may occasionally disagree with tax authorities on the technical interpretation of a particular area of tax law. The tax charge included in our financial statements is our best estimate of tax liability pending any audits by tax authorities.

We expect there to be a continued focus on tax reform, driven by initiatives of the OECD and the EC to address the tax challenges arising from digitalization of the economy. Together with domestic initiatives around the world, these may result in significant changes to established tax principles and an increase in tax authority disputes. Regardless of their merit or outcomes, these may be costly, divert management attention and adversely impact our reputation and relationship with key stakeholders.

Anti-bribery and corruption (ABAC)

Risk definition

The ABAC risk comprises five sub-risk areas:

- Bribery of public officials by GSK;
- Bribery of commercial and other non-public entities by GSK;
- Bribery by third parties acting on behalf of GSK;
- GSK employees receiving and/or requesting bribes and/or other undue personal benefit;
- Other corruption-non-compliance with laws and regulations related to money laundering or facilitation of tax evasion by third parties/clients/partners.

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, failure to prevent bribery or corruption could have substantial implications for GSK's reputation and the credibility of senior leaders and might erode investor confidence in our governance and risk management. It could also lead to legal and financial penalties.

Context

The overall environment for ABAC remains challenging. Countries are holding individuals, as well as corporations, accountable by increasing the employer duty of care. Divergence of legislation, increasing political protectionism, social inequality and pricing pressures are making compliance harder. Society is holding corporations to ever higher standards, with technology providing a rapid and anonymous avenue for dissemination of previously confidential information and even for damaging false reports.

Enforcement actions and penalties have increased across the globe with the focus on use of third-party intermediaries. Proposed EU legislation would require businesses to carry out due diligence on potential human rights and related-environmental impacts of their operations and supply chains, imposing a legal standard of care. In addition, the impact of COVID-19 on businesses, including disruptions in manufacturing, the supply chain, import/export and travel, etc., could increase the risk of bribery and corruption.

Supportive aspects of the external environment include an increase in transparency and collaboration among enforcement authorities with the aim of reducing bribery and corruption globally. Advances in technology are also providing better platforms to streamline processes and detect potential issues.

Commercial practices and pricing

Risk definition

Failure to engage in commercial activities that are consistent with the letter and spirit of the law, industry regulations, or the Group's requirements relating to sales and promotion of our medicines and vaccines; appropriate interactions with healthcare professionals/organizations and patients; legitimate and transparent transfers of value; and pricing and competition (or antitrust) regulations in commercial practices, including trade channel activities and tendering business.

Risk impact

Failure to engage in commercial activities that are consistent with the letter and spirit of the law, industry regulations, or the Group's requirements relating to sales and promotion of medicines and vaccines; with appropriate interactions with healthcare professionals (HCPs), organizations and patients; with legitimate and transparent transfers of value; and with pricing and competition (or antitrust) regulations in commercial practices, including trade channel activities and business tendering, could, materially and adversely affect our ability to deliver our strategy and long term priorities. Additionally, it may result in incomplete awareness of the risk/benefit profile of our products and possibly suboptimal treatment of patients and consumers; 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. 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 continue to evolve our business operations to operate globally in a highly regulated and extremely competitive biopharma industry, where our peers may make significant product innovations and technical advances and intensify price competition. In the Consumer Healthcare marketplace, where our partners are classic retail, pharmacies and, increasingly, online platforms, we face similarly robust competition. In this challenging environment, to achieve our strategic objectives, we must continue to develop commercially viable new products and deliver additional uses for existing products that address the needs of patients, consumers, HCPs and payers.

In common with other pharmaceutical, vaccine and consumer healthcare companies we are embracing opportunities in an evolving digital landscape while facing uncertain market conditions due to the global COVID-19 pandemic and continued downward price pressure in major markets.

Developing new pharmaceutical, vaccine and consumer healthcare products is a costly, lengthy and uncertain process. A candidate product may fail at any stage, including after the investment of significant economic and human resources. Our competitors' products or pricing strategies, or our potential failure to develop commercially successful products or deliver additional uses for existing products, could materially and adversely affect our ability to achieve GSK's strategic objectives.

We are committed to the ethical and responsible commercialization of our products in support of our purpose to improve the quality of human life by enabling people to do more, feel better, and live longer. To accomplish this purpose, we engage the healthcare community in various ways to provide important information about our medicines and vaccines.

By promoting our approved products, we seek to ensure that HCPs globally have access to the information they need, that patients and consumers have the facts and products they require, and that products are prescribed, recommended or used in a manner that provides maximum healthcare benefits. We are committed to communicating information related to our approved products in a responsible, legal and ethical manner.

Non-promotional engagement

Risk definition

Failure to engage in non-promotional activities that are consistent with external regulations, internal policies, and GSK values regarding scientific engagement with healthcare professionals and patients, including i) communications relating to our medicines or associated disease areas; ii) appropriate conduct of interactions; and iii) legitimacy and transparency of those interactions.

Risk impact

Without controls in place, the risk could result in reputational damage, governmental or regulatory investigations (e.g., regarding real, perceived or disguised promotion including off-label and prior-authorization promotion, and real or perceived provision of medical advice), criminal investigations and penalties, civil litigation or competitor complaints affecting our financial results and reducing the trust of the general public, patients, healthcare professionals, payers, regulators and governments. At the same time, failure to engage fully and appropriately could also result in reputational damage, patient harm and financial loss.

Context

Non-promotional engagements are diverse activities directed at healthcare professionals, as well as patients, payers and other stakeholders. They aim to improve patient care through the exchange or provision of knowledge on the use of GSK medicines and vaccines and about related diseases. Non-promotional engagement with external stakeholder groups is vital to GSK, as a research-based healthcare company, and necessary for scientific and medical advances. We expect our non-promotional activities to be scientifically sound and accurate, conducted ethically and transparently and compliant with applicable codes, laws and regulations. However, non-promotional engagements are largely unregulated. Therefore, measured risk taking, rooted in sound values, and principles-based decision making, training, communication and monitoring are key to managing the risk and enabling full and appropriate engagement.

Privacy

Risk definition

The failure to collect, secure, use and destroy Personal Information (PI) in accordance with data privacy laws can lead to harm to individuals (e.g. financial, stress, prejudice) and GSK (e.g. fines, operational, financial and reputational).

Risk impact

Non-compliance with data privacy laws globally could lead to harm to individuals and GSK. It could also damage trust between GSK and individuals, communities, business partners and government authorities.

Many countries have increased the enforcement powers of their data protection authorities by allowing them to impose significant fines, impact cross-border data flows, or temporarily ban data processing. Many new country laws also give individuals the right to bring collective legal actions against companies like GSK for failure to comply with data privacy laws.

Context

Data privacy legislation is diverse with limited harmonization or simplification. It is challenging for multinationals to standardize their approach to compliance with data privacy laws. Governments are enforcing compliance with data privacy laws more rigorously. The focus on the ethical use of personal information is growing, over and above compliance with data privacy laws, due to an increase in the volume of data processed and advances in technology.

Workforce protection and effective privacy controls for research during the COVID-19 pandemic are creating unique challenges. Additionally, new data privacy laws, enforcement activities and court decisions – like the Court of Justice of the European Union ruling for Schrems II – are creating uncertainties for international data transfers and potential localization requirements.

Research practices

Risk definition

Research Practices risk is the failure to adequately conduct ethical and sound pre-clinical and clinical research. In addition, it is the failure to engage in scientific activities that are consistent with the letter and spirit of the law and industry, or the Group’s requirements. It comprises the following sub-risks: Non-Clinical & Laboratory Research; Human Subject Research; Data Integrity; Care, Welfare & Treatment of Animals; Human Biological Samples Management; Data Disclosure; Regulatory Filings & Engagement; and Patents.

Risk impact

The potential 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 authorization. Any of these could materially and adversely affect our financial results and damage the trust of patients and customers.

Context

Research involving animals can raise ethical concerns. In many cases, however, research in animals is the only way to investigate the effects of a potential new medicine in a living body other than in humans. Animal research provides critical information about the causes and mechanisms of diseases and therefore remains a vital part of our research. We continually seek ways in which we can minimize our use of animals in research, development and testing, while complying with regulatory requirements and reducing the impact on the animals used.

Human subject research, including clinical trials in healthy volunteers and patients, assess and demonstrate an investigational product’s efficacy and safety, or further evaluate the product once it has been approved. We disclose this research externally, according to regulations, ethical principles and industry commitments.

We also work with human biological samples, which are fundamental to the discovery, development and safety monitoring of our products. GSK is committed to ensuring that human biological samples are managed in accordance with relevant laws, regulations and ethical principles, in a manner that respects the interests of sample donors.

The integrity and governance of our data is essential to success in all stages of the data lifecycle, including design, generation, recording and management, analysis, reporting, storage and retrieval. Our R&D data are governed by legislation and regulatory requirements. 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 and governance could compromise GSK’s R&D efforts and negatively impact our reputation.

There are innate complexities and interdependencies in regulatory filings, particularly given our global R&D footprint. Ever changing and increasingly stringent submission requirements continue to increase the complexity of worldwide product registration. The supply of GSK medicines to patients is dependent on the ongoing compliance and maintenance of licenses across many geographies, whose requirements and timelines differ. The secure management of the high volume of lifecycle changes to these licenses, and their renewal, is critical to compliant supply. Failure to maintain our licenses will directly impact patients and company revenue.

A wide variety of biological materials are used by GSK in the discovery, research and development of our assets. 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 R&D.

We support the principles of access to, and benefit sharing of, genetic resources as outlined in the CBD and the Nagoya Protocol. We also recognize the importance of appropriate, effective and proportionate implementation measures at national and regional levels.

Patent rights are awarded to protect innovation and play an important role in providing a competitive advantage in the market for a limited period of time. Any loss of patent protection in a market for GSK's products developed through our R&D – including reducing the term, availability or scope of patent rights – could materially and adversely affect our financial results in that market. Inadequate patent or data exclusivity protection which could lead, for example, to competition from manufacturers of generic or biosimilar pharmaceutical products could limit our opportunity to rely on such markets for future sales growth. This could also materially and adversely impact our financial results.

Following expiration of certain intellectual property rights, a generic or biosimilar manufacturer may lawfully produce a competing copy 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.

Environment, health and safety

Risk definition

Failure in management of:

- execution of hazardous activities;
- GSK's physical assets and infrastructure;
- handling and processing of hazardous chemicals and biological agents;
- control of releases of substances harmful to the environment in both the short and long term;

leading to incidents which could disrupt our R&D and Supply activities, harm employees, harm the communities and harm the local environments in which we operate.

Risk impact

Failure to manage EHS risks could lead to significant harm to people, the environment and the communities in which we operate; fines; inability 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

GSK is subject to the 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. Overall, our control framework for managing EHS risk is effective.

Environmental sustainability

Risk definition

Failure in the management of:

- Physical climate and environmental risks;
- Current and future regulatory requirements for environmental policies and taxes;

- Delivery and performance of management environmental objectives;

leading to: reduced supply chain resilience; product life cycle management issues, loss of trust/reputation with employees, investors, customers, regulators and other stakeholders; increased costs; loss of sales or market access; negative impacts on the environment.

Risk impact

GSK recognizes that the way we respond to climate change and manage environmental risks impacts our ability to supply products to patients and consumers and could lead to harm to the environment and impact our reputation.

Failure to meet fast-evolving regulatory requirements and stakeholder expectations could result in litigation or regulatory actions, which may materially and adversely impact our financial results.

Context

It is increasingly understood that the effects of climate change and nature loss, which are themselves interconnected, are impacting human health. Internal and external expectations for companies to address their impact on the environment are increasing; as are the effects of climate change on operational resilience, in regard to access to energy, water and the natural resources used in products, along with potential cost increases from any regulatory changes or environmental taxes.

Information Security

Risk definition

The risk that unauthorized disclosure, theft, unavailability or corruption of GSK's information or key information systems may lead to harm to our patients, workforce and customers, disruption to our business and/or loss of commercial or strategic advantage, damage to our reputation or regulatory sanction.

Risk impact

Failure to adequately protect GSK's information, or key information systems, may cause harm to our patients, workforce and customers, disruption to our business and/or loss of commercial or strategic advantage, regulatory sanction, or damage to our reputation.

Context

The overall information security environment is challenging, because of the difficulty of keeping pace with increasingly sophisticated cyber threats. This is due to many factors including, the complexity of large regulated organizations; the well-resourced nature of hacking activities; and the increasing demands for accountability of data handled by companies. We continue to reassess GSK's reliance on interconnectivity with third party contractors, partners and suppliers. The COVID-19 pandemic has emerged as another significant external factor impacting how information security is managed at GSK. COVID-19-related threats include an increase in ransomware attacks against the healthcare sector, as hackers have used the opportunity to disrupt critical healthcare operations and, in some cases, seize healthcare research related to COVID-19 vaccines and treatments.

GSK operates a highly-connected information network which holds confidential research and development, manufacturing, commercial, workforce and financial data. This means that our systems and information have been and will continue to be the target of cyberattacks. We continue to consolidate information systems to reduce attack points and enable more focused controls. GSK's strategic approach to digital analytics will further increase our dependency on digital assets and distributed data. Our continued analysis and assessment of GSK's critical data assets and the threats to those assets will require a continuous re-evaluation of emerging risks to GSK. Mitigating actions identified in these areas include the secure deployment and operation of GSK resources in high-risk markets, the risk posed by GSK having data in the Cloud, and the potential for complexity resulting from agile business-led IT development across the enterprise.

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.

Risk impact

We recognize how important the continuity of supply of our products is to the patients and consumers who rely on them. A material interruption of supply could lead to litigation or regulatory action, including exclusion from healthcare programs and financial penalties that might adversely affect the Group's financial results. GSK's international presence, and those of our partners, expose our workforce, facilities, operations and IT to potential disruption from natural events (e.g., storms and earthquakes), man-made events (e.g., the imposition of trading barriers at short notice, civil/political unrest, terrorism and cyberattacks), and public health emergencies (e.g., the global COVID-19 pandemic). It is therefore vital 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 of our manufacturing and distribution network to deliver products could lead to litigation or regulatory action, such as product recalls and seizures, interruption of supply, delays in 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. These include active pharmaceutical ingredients, antigens, intermediates, commodities, and components for developing, manufacturing and packaging pharmaceutical, vaccine and consumer healthcare products. Our third-party oversight includes the outsourcing of operations, such as contract manufacturing and clinical research organizations, that provide manufacturing and support development of key products on our behalf.

Although we undertake risk mitigation, we recognize that certain events could still result in delays or service interruptions. We use effective crisis management and business continuity planning to ensure the health and safety of our people and to minimize the impact on supply, by maintaining functional operations in the event of a natural or man-made disaster, or a public health emergency. Drug shortages are reported to appropriate regulatory authorities such as the US Food and Drug Administration for transparency and to solicit feedback on risk mitigation.

Supply performance expectations increased during the COVID-19 pandemic as governments sought to secure supply for key medicines and vaccines. We prioritized, and aligned behind, the manufacture and supply of these pandemic medicines with our suppliers, leveraging strategic stocks and modifying supply routes to avoid disrupting the availability of our finished products.

We also participated in the EU's new reporting system for anticipated drug shortages, introduced during the pandemic to proactively resolve supply issues before they potentially impacted hospital intensive care units.

Transformation

Risk definition

Failure to deliver the plan for successful transformation and separation of GSK into two competitive standalone companies: New GSK, a biopharma company, and new Consumer Healthcare.

Risk impact

The failure to manage the increasing macro level risk due to COVID-19 in relation to the delivery of the transformation plan could materially and adversely affect our ability to deliver GSK's strategy and long-term priorities.

Context

In February 2020, GSK announced a new 'Future Ready' program to prepare for its separation into two companies: New GSK, a biopharma company with an R&D approach focused on science related to the immune system, the use of genetics and new technologies, and a new leader in consumer healthcare. As GSK increases investment in R&D and new product launches, the two-year separation program aims to drive a common approach to innovation across modalities with improved capital allocation; to align and improve the capabilities

and efficiencies of global support functions to support New GSK; to further optimize the supply chain and portfolio, including divesting non-core assets; and to prepare Consumer Healthcare to operate as a standalone company. Once complete, the outlook of both companies will have been fundamentally strengthened, making them more efficient, modern and automated, with future skills and capabilities that will extend beyond the transition timeline. See “Risks associated with the Separation of the Consumer Healthcare Business” below.

Risks associated with COVID-19

The potential impact of the COVID-19 pandemic on GSK’s trading performance and all our principal risks has been assessed. Up to the date of this annual report on Form 20-F, the pandemic has, as anticipated, impacted the Group performance during the year primarily in demand for vaccines as a result of ongoing containment measures impacting customers’ ability and willingness to access vaccination services across all regions. We anticipate that governments’ prioritization of COVID-19 vaccination programs will continue to impact our Vaccines business. We continue to monitor the situation closely, as this continues to be a dynamic and uncertain situation, with the ultimate severity, duration and impact unknown at this point including potential impacts on trading results, clinical trials, supply continuity and our employees. The situation could change at any time and there can be no assurance that the COVID-19 pandemic will not have a material adverse impact on the future results of the Group.

Risks associated with the Separation of the Consumer Healthcare Business

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 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 is 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 is 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).