

# What science can do

AstraZeneca 

AstraZeneca Risk Supplement 2024



# Risk

## Risks and uncertainties

In this supplement, we describe the risks and uncertainties that we consider material to our business, in that they may have a significant effect on our financial condition, results of operations and/or reputation.

These risks are not listed in any particular order of priority. We believe that the forward-looking statements about AstraZeneca, identified by words such as 'anticipates', 'believes', 'expects' and 'intends', and that include, among other things, Future prospects as described in the Financial Review from page 67 of AstraZeneca's Annual Report and Form 20-F Information 2024, are based on reasonable assumptions. However, forward-looking statements involve inherent risks and uncertainties such as those summarised below. They relate to events that may occur in the future, that may be influenced by factors beyond our control and that may have actual outcomes materially different from our expectations. Therefore, other risks, unknown or not currently considered material could have a significant adverse effect on our financial condition, results of operations and/or reputation.

### Product pipeline risks

### Impact

#### Failure or delay in the delivery of our pipeline or launch of new medicines

Our continued success depends on the development and successful launch of innovative new drugs.

The development of pharmaceutical product candidates is a complex, risky and lengthy process involving significant resources. Projects have failed, and may fail in the future, at any stage of the process due to various factors, including: failure to obtain the required regulatory or marketing approvals, unfavourable clinical efficacy data, safety concerns, failure to demonstrate adequate cost-effective benefits to regulatory authorities and/or payers, and the emergence of competing products.

Launch activities have been delayed, and may be delayed in the future, by a number of factors, including: adverse findings in preclinical or clinical studies, regulatory demands, price negotiation, large-scale natural disasters or global pandemics, competitor activity and technology transfer.

In addition to developing products in-house, we continue to expand our portfolio through licensing arrangements and strategic collaborations which may not ultimately be successful.

Failure or delay in development of new product candidates could damage the reputation of our R&D capabilities, and adversely affect our future business and results of operations.

Delays to launches can lead to excess expenses in the manufacture of pre-launch inventories, marketing materials and salesforce training. For the launch of products that are seasonal in nature, delays in regulatory approvals or manufacturing may delay launch to the next season which, in turn, may significantly reduce the return on costs incurred in preparing for the launch for that season. Furthermore, in immuno-oncology in particular, speed to market is critical given the large number of clinical trials being conducted by competitors. Delay of launch can also erode the term of patent exclusivity.

Competition from other pharmaceutical companies means that we may have to pay a significant premium over book or market values for our acquisitions. Failure to complete collaborative projects in a timely, cost-effective manner may limit our ability to access a greater portfolio of products, intellectual property (IP), technology and shared expertise. In many cases, we make milestone payments in advance of the commercialisation of the products, with no assurance of recouping costs.

#### Failure to meet regulatory or ethical requirements for medicine development or approval

We are subject to laws and regulations that control our ability to market our pharmaceutical products. Our development programmes must meet many standards to prove our products are safe, effective and of high quality. Health authorities, such as the FDA in the US and the European Medicines Agency in the EU, can refuse to approve our products or require us to conduct additional clinical trials or scientific testing before they will approve them for marketing. Many factors influence health authority decisions to approve or reject a marketing application for a pharmaceutical product. These include advances in science and technology, new laws, regulations and policies, and different standards for evaluating safety and effectiveness.

Delays in regulatory approvals could delay our ability to market our products and may adversely affect our revenue. Also, post-approval requirements, including additional clinical trials, could cause increased costs. We seek to manage these risks, but policymaking by governments and health authorities can be unpredictable and unforeseen circumstances, such as public health emergencies, may strain health authority resources and delay the approval of our products.

Following approval, a health authority may require us to conduct additional clinical trials or scientific testing to address concerns raised after patients have used our products in the marketplace. New data may impact a product's approval status or lead to labelling changes that limit the use of a product.

□ More details of projects that have suffered setbacks or failures during 2024 can be found in the Therapy Area Review from page 16 of AstraZeneca's Annual Report and Form 20-F Information 2024.

See also Failure to achieve strategic plans or meet targets or expectations on page 66.

## Risk *continued*

### Commercialisation risks

### Impact

#### Failures or delays in the quality or execution of the Group's commercial strategies

Maximising the commercial potential of our new products underpins the success of our strategy and the delivery of our short- and medium-term targets. We may ultimately be unable to achieve commercial success for various reasons, including:

- Difficulties in manufacturing sufficient quantities of the product
- Any price control measures imposed by governments and healthcare authorities
- Patient access to healthcare
- Diagnosis rates
- Erosion of IP rights
- Failure to show a differentiated product profile
- Changes in prescribing habits.

The ability to successfully carry out business in emerging markets can be more challenging than in established markets. Such challenges may include:

- Volatility in economic or political climates
- Inadequate protection against crime (including counterfeiting, corruption and fraud)
- Inadvertent breaches of local and international law.

Failure to execute our commercial strategies or achieve the level of sales anticipated for a medicine could materially adversely impact our business or results of operations.

Failure to leverage potential opportunities or appropriately manage risks in emerging markets may materially adversely affect our reputation, business or results of operations.

#### Pricing affordability, access and competitive pressures

At AstraZeneca, our approach to pricing balances the priorities of patients, their physicians, payers, society and our business. Our four guiding principles – Access, Value, Sustainability and Equity – aligned to our overarching Company Values, form the cornerstones of our brand pricing strategies. Our prices are rooted in the assurance of our high-quality science, and the benefit this brings to patients. They also reflect holistic value, in the context of healthcare systems and market dynamics, affordability and equity; so that we can adapt our prices across the more than 100 countries in which we operate and help support long-term healthcare system resilience.

Our pricing approach, as described in the previous paragraph, is a key contributor to our success. However, there are various external risk factors that could compromise our ability to execute our pricing strategies as planned. The market access environment is highly complex and subject to dynamic economic, political and social pressures. Globally, there are increasing cost-containment measures, greater calls for net price and R&D cost transparency, as well as early discussions toward pooled procurement mechanisms beyond emergency countermeasures and essential medicines. We have also experienced the first and second rounds of drug pricing system reforms in the US, with associated uncertainty on the long-term impact.

Continued deterioration of, or lack of improvement in, socio-economic conditions could adversely affect supply and/or distribution in affected countries and the ability or willingness of customers to purchase our medicines, putting pressure on price and/or volumes. This could adversely affect our business or results of operations, for example, those healthcare systems most severely impacted by downturn may seek alternative ways to settle their debts at a discount. Other customers may cease to trade, which may result in losses from writing off debts or a reduction in demand for products. Across the industry, the Inflation Reduction Act (IRA) in the US and joint procedures to evaluate comparative clinical effectiveness in the EU could reduce the value of certain products sooner than planned and impact the R&D pipeline as companies seek to avoid investing in lower yield products.

### Supply chain and business execution risks

### Impact

#### Failure to maintain supply of compliant, quality medicines

We may experience challenges, delays or interruptions in the manufacturing and supply of our products for various reasons, including:

- Supply shortages or delays in construction of facilities to support future demand of our products caused by significant unforecasted demand growth or supply chain disruptions (e.g. natural disasters, climate impacts, COVID-19, conflict or political unrest).
- The inability to supply products due to a product quality failure or regulatory compliance action such as licence withdrawal, product recall or change of regulatory standards (e.g. nitrosamines, where regulators have been introducing new limits/expectations for regulatory filings).

It is necessary for us to meet all regulations, including compliance with Good Manufacturing Practices and Good Distribution Practices and comparable regulatory dossier conditions of approval in all countries in which our products are licensed, manufactured or sold.

We rely significantly on third parties for the timely supply of goods (e.g. active ingredients and packaging components, many of which are difficult to substitute in a timely manner or at all).

Supply chain difficulties may result in product shortages, which could lead to lost Product Sales and materially affect our reputation and results of operations.

Failure to comply with all manufacturing regulations can result in negative regulatory inspection findings that could lead to the halt of manufacturing, and/or product seizure, debarment or recalls which could have an adverse effect on our business, financial condition and results of operations.

In the event of insolvency of third-party suppliers, it would be difficult to substitute in a timely manner or at all.

## Risk *continued*

Supply chain and business execution risks *continued*

Impact

### Illegal trade in the Group's medicines

The illegal trade of pharmaceutical products, including counterfeiting, tampering, theft and illegal diversion (where products are found in a market where we did not send them and where they are not approved to be sold) may lead to a loss of public confidence in the integrity of medicines.

The incidence of illegal trade could materially adversely affect our reputation and financial performance, and pose a direct risk to patient safety. In addition, concern about this issue may cause some patients to stop taking their medicines, with consequential risks to their health.

If we are found liable for breaches in our supply chains, authorities may take action, financial or otherwise, that could restrict the distribution of our products.

### Reliance on third-party goods and services

A significant proportion of AstraZeneca's annual costs relates to spend with third-party suppliers. The level of spend supports the length of our value chain from discovery to manufacture and commercialisation of our medicines.

Many of our business-critical operations are outsourced to third-party providers. We are, therefore, heavily reliant on these third parties to get medicines to patients, comply with applicable laws and regulations, while also ensuring prudent use of AstraZeneca financial resources.

Failure to successfully secure, onboard and manage outsourced services, particularly with continued inflationary pressures, or the failure of outsourced providers to deliver timely services, and to the required level of quality, could materially adversely affect our reputation, our financial condition and operating results as well as our ability to deliver medicines to patients.

Failure to effectively manage third-party suppliers when external factors, including geopolitical tensions or raw materials and components shortages, place increased pressure on AstraZeneca's ability to purchase goods and services may lead to major business disruption.

Any breach of security, whether physical, cyber or data related, or failure of these third parties to operate in a way that is consistent with laws or regulations, may lead to regulatory penalties, materially affect the results of operations and adversely impact our reputation.

### Failure in information technology or cybersecurity

IT systems enable critical business functions which are increasingly dependent on partner and vendor IT stability and data integrity. High availability IT systems remain a business imperative, providing our workforce with continuous access to collaboration environments, global communications channels, applications and data. In addition to availability and reliability, these systems must comply with provisions specified in data security, privacy and individual protection laws.

Data is a commodity we prioritise continued access to and protection of. It is often characterised as strictly confidential information and examples of strictly confidential data include clinical trial records, personal information, IP, R&D data, and compliance information. IT systems and data are potentially vulnerable to service interruptions and security breaches via attacks by malicious third parties or intentional or inadvertent actions by our employees or vendors. Attempts to exploit AstraZeneca's IT systems and data are increasingly sophisticated. Threat actors include organised criminal groups, 'hacktivists', nation states, employees and others. Privacy legislation includes obligations to report data protection breaches to regulators and affected individuals within expedited timeframes.

The internet is our primary critical business transaction channel. Internet availability is increasingly at risk due to geopolitical tensions and conflict.

Disruption to our IT systems and/or the internet (including breaches of data security or cybersecurity, failure to integrate new and existing IT systems) or failure to comply with additional requirements under applicable laws, could harm our reputation and materially adversely affect our financial condition or operations. While we invest heavily in the protection of our data and IT, we may be unable to prevent hardware or software failures or breaches which could result in disclosure of confidential information, damage to our reputation, regulatory penalties or sanctions, or financial loss.

The inability to back-up and restore data effectively could lead to permanent loss of data that could, in turn, result in non-compliance with applicable laws and regulations and otherwise harm our business. Data loss could lead to public disclosure of confidential information which may damage our reputation, materially affect our business or results of operations, and expose us to legal risks and/or additional legal obligations. Public disclosure of sensitive information could materially adversely affect our reputation and business or operations' results.

Cybersecurity insurance coverage limits may not protect against any future claim or claim proceeds may be delayed.

Failure to comply with regulatory disclosure requirements could cause reputational damage and a loss of public trust.

## Risk *continued*

Supply chain and business execution risks *continued*

Impact

### Failure of critical processes

Unexpected events and/or events beyond our control could result in the failure of critical processes within the Group or at third parties on whom we are reliant.

The business faces threats to business continuity from many directions. Examples of material threats include:

- Disruption to our business or the global markets if there is instability in a particular geographic region, including as a result of war, terrorism, pandemics, armed conflicts, riots, unstable governments, civil insurrection or social unrest.
- Natural disasters in areas of the world prone to extreme weather events, which may increase in frequency or severity as a result of climate change.
- Cyber threats similar to those detailed in the 'Failure in information technology or cybersecurity' section above.

Crystallisation of such material threats may heighten certain other risks, such as those relating to the delivery of the pipeline, launch of new medicines, or the manufacture and supply of medicines, and may lead to loss of revenue and have a materially adverse impact on our financial results.

### Failure to collect and manage data and AI in line with legal and regulatory requirements and strategic objectives

Data is increasingly recognised as being AstraZeneca's most valuable commodity. There is an increasing range of legislative and regulatory requirements to manage data across all countries where we conduct business. The requirements may impact certain types of data such as personal data, the way that we conduct business, such as restricting the movement of data between countries or jurisdictional regions, or how we make use of new technological capabilities such as AI. In addition, geopolitical changes may require changes to how AstraZeneca manages data.

Beyond legal and regulatory requirements, achieving strategic objectives will require good management of data across the enterprise. As our organisation increasingly relies on data, including sensitive data relating to health and genomics, a failure to properly understand personal and collective accountabilities for managing data to maximise its value, or failure to address data risks, will reduce our ability to execute at pace and deliver strategic objectives.

AI technologies present significant opportunities and risks to our business. Harnessing AI's transformative potential may enable AstraZeneca to speed up the discovery and development of new drugs, optimise our manufacturing processes, drive efficiencies and productivity, and accelerate our growth. Failure to exploit these opportunities may put AstraZeneca at a competitive disadvantage.

AstraZeneca is investing significant resources into AI experimentation, development and deployment across many parts of our business. As we scale our use of AI, it is possible not all investments will succeed.

AI technologies may exacerbate existing risks, like those risks associated with data privacy, cybersecurity and IP. AI also introduces new risks due to the autonomous nature of the technology, the ease at which AI-enabled decision making can be scaled up, and the commercial pressures to adopt AI. AI systems can amplify biased and discriminatory decision making, perform unreliably and malfunction, generate insights which are difficult to interpret and explain, and cause direct harm to individuals or groups. These risks may become more significant as we increasingly utilise AI to inform, augment and automate decision making and processes in sensitive areas (e.g. clinical trials and medical decision making).

The adoption and exploitation of AI is occurring under the backdrop of intense global media scrutiny, heightened political attention and low levels of public trust and understanding. There is also a range of new AI regulations being adopted and implemented worldwide, including in the EU, China and the US.

Despite taking measures designed to ensure compliance with applicable privacy- and AI-related laws and regulations by our personnel and our third parties, non-compliance has occurred and may occur again. If future instances of non-compliance are deemed significant, these may attract material regulatory sanctions or fines and corresponding reputational damage, orders to stop certain processing of personal data, or legal action on behalf of impacted individuals. Further, failure to protect personal data could lead to a competitive disadvantage, loss of trust from our stakeholders, including patients, and prevent us from delivering our strategic objectives.

If the scope of data-related laws is expanded or if the interpretation or enforcement of existing laws change or new privacy laws are implemented, AstraZeneca and its third-party vendors may be required to change their business practices or data processing practices and policies. This may lead to substantial compliance-related costs or materially adversely impact our business and financial condition.

Our failure to use AI technologies in a way that maintains trust, quality and control in our business activities would pose reputational, legal, regulatory and financial risks to AstraZeneca. Investments in AI may not realise the benefits that were anticipated.

### Failure to attract, develop, engage and retain a diverse, talented and capable workforce

We rely heavily on recruiting and retaining talented employees with a diverse range of skills and capabilities to meet our strategic objectives. Externally there is intense competition for well-qualified individuals, as the supply of people with certain skills or in specific geographic regions may be limited.

Ensuring our employees are continually developed and engaged with strategic objectives embeds commitment across the workforce.

The inability to attract and retain highly skilled personnel may weaken our succession plans for critical positions, impact the implementation of our strategic objectives and ultimately result in the failure of our business operations.

Failure to develop and engage our workforce could result in business disruption, a loss of productivity and higher turnover rates, all of which could materially adversely affect our business.

Focus in 2025 will be to continue building talent and capability across our global hubs to ensure we are best positioned to support science and the business towards the Ambition 2030.

## Risk *continued*

Legal, regulatory and compliance risks

Impact

### **Failure to meet our sustainability targets, regulatory requirements and stakeholder expectations with respect to the environment**

Environmental issues will become more material as healthcare systems continue to adopt net-zero climate targets.

Investors, governments and non-governmental organisations will increasingly scrutinise our environmental targets and performance.

Environmental considerations are becoming embedded in the public procurement of medicinal products and devices.

Specific materials used to manufacture medicines, or used as excipients or propellants, are coming under increased regulation and may be subject to time-limited exemptions or potential phase-out.

The physical impacts of climate change could impact the resilience of our business operations and supply chain.

Investors are increasingly focusing on environmental issues. We continue to see an increased requirement to quantify the impact of specific environmental issues and to disclose our strategy, targets and performance.

Failure to maximise our environmental sustainability credentials could expose us to increased regulatory risk and put us at a commercial disadvantage relative to our peers. This could adversely impact our financial results and lead to reputational damage.

Failure to proactively manage the physical risks associated with climate change could impact the resilience of our operations and supply chain. This could result in supply interruptions, loss of stock and adversely impact our financial results.

### **Safety and efficacy of marketed medicines is questioned**

Our ability to accurately assess, prior to launch, the eventual safety or efficacy of a new product once in broader clinical use can only be based on data available at that time, which is inherently limited due to relatively short periods of product testing and relatively small clinical study patient samples.

Any unforeseen safety concerns or adverse events relating to our products, or failure to comply with laws, rules and regulations relating to provision of appropriate warnings concerning the dangers and risks of our products that result in injuries, could expose us to large product liability claims, settlements and awards, particularly in the US. Adverse publicity relating to the safety of a product, or of other competing products, may increase the risk of product liability claims.

Serious safety concerns or adverse events relating to our products could lead to product recalls, seizures, loss of product approvals, declining sales and interruption of supply, and could materially adversely impact patient access, our reputation and financial revenues. Significant product liability claims could also arise which could be costly, divert management attention, or damage our reputation and demand for our products.

Unfavourable resolution of such current and similar future product liability claims could subject us to enhanced damages, consumer fraud and/or other claims, including civil and criminal governmental actions. This could require us to make significant provisions in our accounts relating to legal proceedings and could materially adversely affect our financial condition or results of operations, particularly where such circumstances are not covered by insurance.

### **Adverse outcome of litigation and/or governmental investigations**

Our business is subject to a wide range of laws and regulations around the world. We have been, and may continue to be, subject to various legal proceedings and governmental investigations.

Actual or perceived failure to comply with laws or regulations may result in AstraZeneca and/or its employees being investigated by government agencies and authorities and/or in civil legal proceedings. Relevant authorities have wide-ranging administrative powers to deal with any failure to comply with laws, regulations or continuing regulatory oversight, and this could affect us, whether such failure is our own or that of our contractors or external partners. In particular, the manufacturing, marketing, exportation, promotional, clinical, pharmacovigilance and pricing practices of pharmaceutical manufacturers, as well as manufacturer interaction with regulatory agencies, purchasers, prescribers and patients, are subject to extensive regulation, litigation and governmental investigation. Moreover, such laws, rules and regulations are subject to change.

Many companies, including AstraZeneca, have been subject to legal claims asserted by federal and state governmental authorities and private payers and consumers, which have resulted in substantial expense and other significant consequences. Governmental investigations or proceedings could result in civil or criminal sanctions and/or the payment of fines or damages. Civil litigation, particularly in the US, is inherently unpredictable, and unexpectedly high awards for damages can result from an adverse result. In many cases, litigation adversaries may claim enhanced damages in extremely high amounts. Government investigations, litigations, and other legal proceedings, regardless of the outcome, could be costly, divert management attention, or damage our reputation and demand for our products.

Unfavourable resolutions to current and similar future proceedings against us that could subject us to criminal liability, fines, penalties or other monetary or non-monetary remedies, including enhanced damages, require us to make significant provisions in our accounts relating to legal proceedings and could materially adversely affect our business or results of operations.

□ Details of material litigations and governmental investigations can be found in Note 30 to the Financial Statements from page 203 of AstraZeneca's Annual Report and Form 20-F Information 2024.

## Risk *continued*

Legal, regulatory and compliance risks *continued*

Impact

### IP risks related to our products

IP protection provides the foundation for continued investment in developing innovative medicines to improve patient health. However, the pharmaceutical industry is experiencing pressure from governments and other healthcare payers to impose limits on IP protections in an effort to manage healthcare costs. Additionally, policymakers are progressively leveraging regulations to expedite the approval of generic drugs and encourage generic drug utilisation. These policies may drive accelerated utilisation of generic alternatives to our products following expiry or loss of our IP rights. We also recognise increasing use of compulsory licensing in some countries in which we operate.

We are subject to numerous patent challenges relating to various products or processes and assertions of non-infringement of our patents. A loss in any of these challenges could result in loss of patent protection on the covered product and a risk to the revenue generated by the product. We also face the risk that our products may be found to infringe patents owned or licensed by third parties and we may be subject to monetary damages or compelled to cease sales of the infringing product, resulting in a potential risk to revenue. These challenges threaten the value of our investment in pharmaceutical development.

If we are unable to obtain, defend and enforce our IP, we may experience accelerated and intensified competition. Also, if our products are found to infringe a third-party patent, we may be subject to monetary damages or compelled to cease sales of the infringing product. These negative outcomes could have an adverse material impact on our financial results.

Economic and financial risks

Impact

### Failure to achieve strategic plans or meet targets or expectations

When we communicate our business strategy, targets or performance expectations (for example, the expectations described in Future prospects in the Financial Review from page 67 of AstraZeneca's Annual Report and Form 20-F Information 2024), all such statements are forward-looking and based on assumptions and judgements, all of which are subject to significant inherent risks and uncertainties.

To achieve our strategic objectives, we must continue to develop commercially viable new products and successfully integrate new organisations we have acquired. There can be no guarantee that our strategy or expectations will materialise. Any failure to successfully implement our business strategy may frustrate the achievement of our financial targets, which may therefore materially damage our brand, business, financial position or results of operations.

### Geopolitical and/or macroeconomic volatility disrupts the operation of our global business

With an active presence in more than 80 countries, we are subject to political, socio-economic and financial factors around the world. A sustained global economic downturn may adversely impact financial markets and/or exacerbate pressure from governments and other healthcare payers on medicine prices and other cost control measures in order to limit healthcare spending.

Geopolitical tensions may lead to the imposition or escalation of trade controls, tariffs, taxes or other restrictions to market access which may increase our costs or reduce revenues.

A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for medicines and our ability to raise additional capital when needed or on favourable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payers.

Measures taken to limit healthcare spending may lead to lower than anticipated rates of growth in some markets and an adverse impact on revenues and profitability.

Any escalation in barriers to the global free flow of medicines is likely to increase costs to serve affected markets which may lead to downward pressure on margins. While the introduction of severe sanctions is unlikely in relation to medicines, it could occur if matters escalate significantly and could impact processes for the commercialisation of medicines and levels of sales in affected markets.

Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

### Failure in internal control, financial reporting or the occurrence of fraud

Effective internal controls assist in the provision of reliable Financial Statements and the detection and prevention of fraud. Testing of internal controls provides only limited assurance over the accuracy of Financial Statements and may not prevent or detect misstatements or fraud.

The introduction of new legislation such as the failure to prevent fraud offence in the Economic Crime and Corporate Transparency Act (effective from 1 September 2025) may increase regulator focus on fraud.

Significant resources may be required to remediate any deficiency in internal controls. Any such deficiency may trigger related investigations and may result in fines being levied against individual directors or officers. Serious fraud may lead to prosecution of senior management. Any of the foregoing could adversely affect our financial results and lead to reputational damage.

□ Details of material patent litigation matters can be found in Note 30 to the Financial Statements from page 203 of AstraZeneca's Annual Report and Form 20-F Information 2024.

## Risk *continued*

Economic and financial risks *continued*

Impact

### Unexpected deterioration in the Group's financial position

Movements in exchange rates against the US dollar, our reporting currency, impact our reported results. The key currencies of Product Sales and costs are: US dollar, Chinese renminbi, euro, Japanese yen, Swedish krona and pound sterling.

Most of our cash is invested in AAA credit-rated institutional money market funds, fixed income securities issued by government, financial and non-financial entities, and collateralised and non-collateralised bank deposits. Our credit exposure is a mix of US, EU and rest of world default risk across these institutions.

We invest in many projects in an effort to develop a successful portfolio of approved products. Our Consolidated Statement of Financial Position therefore contains significant investments in intangible assets, including goodwill. Our ability to realise value on these investments depends on regulatory approvals, market acceptance, competition, and legal developments.

Our defined benefit post-retirement obligations (primarily in the UK and Sweden) can materially change in value but are largely backed by assets invested in growth and liability hedging portfolios, which hedge some of the risks inherent in liability valuations.

Although we maintain relevant insurance coverage for risks arising within the Group, we may not be able to maintain our insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

Tax law is complex, leading to the risk of different interpretations. Revenue authorities can make conflicting claims to the profits taxed in individual countries leading to double taxation and the potential for fines and penalties. Tax laws can change following action by international bodies such as the Organisation for Economic Co-operation and Development or individual governments.

Foreign exchange rate movements may materially adversely affect our financial condition or results of operations.

In a sustained economic downturn, such institutions may cease to trade and there can be no guarantee that we will be able to access the full value of our investments.

We expect that some of our intangible assets will become impaired in the future. Impairment losses may materially adversely affect our financial condition or results of operations.

Solvency levels could fall, adversely impacting our financial position and requiring higher cash contributions if there are: falls in assets; increases in liability valuations (from falls in bond yields, increases in inflation or lower mortality); or changes in regulations. As liability valuation risks are hedged to a material level in some pension schemes, significant collateral may need to be posted to meet margin requirements, which in extreme circumstances, could lead to a short-term liquidity risk in these pension schemes and a request to the Group to provide temporary liquidity.

Uninsured losses, or those where an insurer denies coverage, could materially adversely affect our financial condition.

The resolution of tax disputes can result in incremental tax costs, a reallocation of profits or losses between jurisdictions, or even double taxation, fines and penalties. They are costly, divert management attention and may adversely affect our reputation.

If tax treaties are withdrawn or amended, or Competent Authorities are unable to reach an agreement that eliminates double taxation, this could materially adversely affect our financial position.

Changes in tax regimes could result in a material impact on the Group's cash tax liabilities and tax charge, resulting in either an increase or a reduction in financial results.

□ Details of financial risk management policies can be found in the Financial Review from page 67 and details of current tax disputes can be found in Note 30 to the Financial Statements from page 203 of AstraZeneca's Annual Report and Form 20-F Information 2024.