Item 3. Key Information

3.A [Reserved]

3.B Capitalization and indebtedness

Not applicable.

3.C Reasons for the offer and use of proceeds

Not applicable.

3.D Risk factors

Our business faces significant risks and uncertainties. You should carefully consider all of the information set forth in this Annual Report and in other documents we file with or furnish to the SEC, including the following risk factors, before deciding to invest in or to maintain an investment in any Novartis securities. Our business, as well as our reputation, financial condition, results of operations, and share price, could be materially adversely affected by any of these risks, as well as other risks and uncertainties not currently known to us or not currently considered material.

Strategic risks

Key products and commercial priorities

Risk description
Failure to deliver key commercial priorities and successfully launch new products

Context and potential impact
Our ability to maintain and grow our business and to replace revenue and income lost to generic, biosimilar and other competition depends heavily on the commercial success of our new or existing key products. The commercial success of these products could be impacted at any time by a number of factors, including pressure from new or existing competitive products, changes in the prescribing habits of healthcare professionals, slower than expected post-launch adoption, unexpected side effects or safety signals, supply chain issues or other product shortages, pricing pressure, regulatory proceedings, changes in labeling, loss of intellectual property protection, and global pandemics. In addition, our revenue and margins could be significantly impacted by the timing and rate of commercial acceptance of new products.

Healthcare professionals, patients and payers may choose competitor products instead of ours for various reasons, including if they perceive them to be better in terms of efficacy, safety, cost, convenience or other reasons. The commercial success of our key products and launches in the face of increasing competition requires significant attention, management focus and resource allocation. Such competition could significantly affect the revenue from our products and our results of operations. This impact could also be compounded to the extent that such competition results in us making significant additional investments in research and development, marketing or sales.

Furthermore, from time to time, we reassess how our business is organized to ensure we have the optimal structure with which to execute our strategy. An inability to successfully implement new organizational structures and operating models could have a material adverse effect on our results of operations and financial condition.

Research and development

Risk description
Failure to successfully prioritize, integrate and execute our research and development programs for new products or new indications for existing products

Context and potential impact
We engage in extensive and costly research and development activities, both through our own internal resources and through collaborations with third parties, in an effort to identify and develop new products and new indications for existing products that address unmet, ever-changing medical needs, while ensuring commercial viability and success. Our ability to grow our business and our product pipeline; to replace sales lost due to branded competition, entry of generics, or other reasons; and to bring products to market that take

advantage of new and potentially disruptive technologies, including cell, gene and radioligand therapies, depends in significant part on the success of these efforts.

Failure to successfully develop our pipeline products is typically the result of the inherent uncertainty of science, suboptimal internal execution, or both. Key elements of internal execution include our ability to prioritize our investments on our highest potential value assets, optimize the transition of assets from research to development, integrate externally acquired assets in an efficient way, and execute the steps in our drug development process that enable our assets to be approved and reimbursed in a timely manner to positively impact clinical practice. We invest in new businesses, products, services and technologies, including artificial intelligence (AI), to achieve our goals, operate our business and reduce the time, effort and expense associated with identifying, developing and commercializing new products. Our investments in new and disruptive technologies may not ultimately achieve the intended benefits, may not result in an adequate return of capital and, in pursuing new strategies, we may incur unanticipated liabilities. For more information, see also “Item 4. Information on the Company—Item 4.B Business overview—Research and development.”

Our new products must undergo intensive preclinical and clinical testing and are approved by means of a highly complex, lengthy, and expensive approval process that varies substantially from country to country and may have very specific requirements for the recruitment of patients for clinical trials. We face increasing and evolving regulatory approval and reimbursement requirements. Additionally, if we fail to successfully progress late-stage assets and the core elements of drug development for key programs, this could have a negative impact on the development of our product pipeline, and ultimately on the success of our business and our financial results.

Another issue we face is the increasing challenge to adequately recruit a sufficient number of patients in the US for clinical trials due to the cost and effort associated with expanding our operations for the recruitment of patients into such trials. As a result, we may be unable to develop the necessary clinical evidence to support the desired indications and product profile for a particular disease that is needed to drive clinical adoption of our new products, and thereby achieve the full potential of our assets (also known as the “target product profile”). Similarly, the post-approval regulatory burden has also increased. These requirements make the maintenance of regulatory approvals for our products increasingly expensive, and further heighten the risk of recalls, product withdrawals, changes to product specifications, loss of market share, and loss of revenue and profitability.

The clinical testing, regulatory processes and post-approval activities described above become more difficult during pandemics, such as the COVID-19 pandemic, as well as during periods of geopolitical and economic uncertainty. This is due to challenges related to recruiting, enrolling and treating patients in clinical trials, as well as ensuring the supply of trial materials. For a further description of the research and development of, and approval processes for, our products, see “Research and development” and “Regulation” under “Item 4. Information on the Company—Item 4.B Business overview.”

Furthermore, our research and development activities must be conducted in an ethical and compliant manner. Among other things, we are concerned with patient safety (both pre- and post-product approval), data privacy, current Good Clinical Practices (cGCP) requirements, data integrity, the fair treatment of patients, diversity and inclusion in the recruitment of patients to clinical trials, and animal welfare. If we fail to properly manage such issues, we risk injury to third parties, damage to our reputation, negative financial consequences as a result of potential claims for damages, sanctions and fines, and the potential that investments in research and development activities may not bring the expected benefits to us.

Pricing, reimbursement and access

Risk description

Pricing and reimbursement pressure, including pricing transparency and access to healthcare

Context and potential impact

Our business has continuously experienced significant pressures on the pricing of our products and on our ability to obtain and maintain satisfactory rates of reimbursement for our products by governments, insurers and other payers. These pressures have many sources, including growth of healthcare costs as a percentage of gross domestic product; funding restrictions and policy changes; and public controversies, political debate, investigations and legal proceedings regarding pharmaceutical pricing. Pressures on pricing may negatively impact both our product pricing and the availability of our products.

In addition, we face numerous cost-containment measures imposed by governments and other payers. These include government-imposed industrywide price reductions, mandatory pricing systems, reference pricing systems, payers limiting access to treatments based on cost-benefit analyses, the importation of drugs from lower-cost countries to higher-cost countries, the shifting of the payment burden to patients through higher co-payments and co-pay accumulator programs, the limiting of physicians’ ability to choose among competing medicines, the mandatory substitution of generic drugs for the patented equivalent, pressure on physicians to reduce the prescribing of patented prescription medicines, increasing pressure on intellectual property protections, and growing requirements for increased transparency on pricing. For more information on price controls, see “Item 4. Information on the Company—Item 4.B Business overview—Price controls.”

Recent trends in our external environment may have an impact on the likelihood of these pricing and reimbursement pressures occurring. Slow economic recovery following the COVID-19 pandemic and the onset of war in certain parts of the world (which is contributing to challenges such as high energy costs and inflation) have led to an increased strain on fiscal budgets in many major economies. In addition, legislative developments such as those in the US (e.g., the Inflation Reduction Act) and in Europe (e.g., the EU Joint Health Technology

Assessment and 2023 EU Pharmaceutical Legislation Update) pose potential further pressures on pricing and timelines for reimbursement in these countries. For example, in August 2023, our cardiovascular drug Entresto was selected for the Medicare Drug Price Negotiation Program in the US and additional Novartis products may be selected for price negotiation programs in the future. These external factors may materially affect our ability to achieve value-based prices; to achieve and maintain an acceptable return on our investments in the research and development of our products; and may impact our ability to research and develop new products.

Alliances, acquisitions and divestments

Risk description
Failure to identify, execute or realize the expected benefits from our external business opportunities

Context and potential impact
As part of our strategy, we evaluate external opportunities that could strengthen our portfolio by acquiring and divesting products, entering businesses or entering into strategic alliances and collaborations. For example, in 2023, we closed the acquisitions of Chinook Therapeutics and DTx Pharma. This strategy is partly dependent on our ability to identify strategic external business opportunities, including assessing the value of the early phase companies, and to close transactions with third parties on acceptable terms and timelines.

Once the terms of a strategic transaction have been agreed with a third party, we may not be able to complete the transaction in a timely manner or at all. In addition, we cannot be sure that pre-transaction due diligence will identify all possible issues that might arise during and after the transaction. Our efforts on such transactions can also divert management’s attention from our existing businesses.

After a transaction is closed, efforts to develop and commercialize acquired or licensed products, to integrate the acquired business or to achieve expected synergies may fail or may not fully meet expectations. This may occur due to difficulties in retaining key personnel, customers and suppliers; failure to obtain marketing approval or reimbursement within expected timeframes or at all; differences in corporate culture, standards, controls, processes and policies; or other factors. Transactions can also result in liabilities being incurred that were not known at the time of acquisition, or the creation of tax or accounting issues. Acquired businesses are not always in full compliance with legal, regulatory or Novartis standards, including, for example, Current Good Manufacturing Practices (cGMP) or cGCP standards, which can be costly and time-consuming to remediate. Furthermore, our strategic alliances and collaborations with third parties may not achieve their intended goals and objectives within expected time frames, or at all. For more information about recent business acquisitions, see “Item 18. Financial Statements—Note 2. Significant transactions.”

Similarly, we cannot ensure that we will be able to successfully divest or spin off businesses or other assets that we have identified for this purpose, or that any completed divestment or spin-off will achieve the expected strategic benefits, operational efficiencies or opportunities, or that the divestment or spin-off will ultimately maximize shareholder value.

Intellectual property

Risk description
Expiry, assertion or loss of intellectual property protection

Context and potential impact
Many of our products are protected by intellectual property rights, which may provide us with exclusive rights to market those products for a limited time, and to enable our purpose of reimagining medicine by sustainably financing our research and development. However, the strength and duration of those rights can vary significantly from product to product and from country to country, and they may be successfully challenged by third parties or governmental authorities.

Loss of intellectual property protection and the introduction of generic or biosimilar competition for a patented branded medicine in a country typically result in a significant reduction in net sales and operating income for the branded product. Such competition can occur after successful challenges to intellectual property rights or the regular expiration of the patent term or other intellectual property rights. Such competition can also result from the entry of generic or biosimilar versions of another medicine in the same therapeutic class as one of our drugs or in a competing therapeutic class, from a Declaration of Public Interest or the compulsory licensing of our intellectual property by governmental authorities, or as a result of a general weakening of intellectual property and governing laws in certain countries around the world. In addition, generic or biosimilar manufacturers may sometimes conduct so-called “launches at risk” of products that are still under legal challenge for infringement, or whose patents are still under legal challenge for validity, before final resolution of legal proceedings.

We also rely in all aspects of our businesses on unpatented proprietary technology, know-how, trade secrets and other confidential information, which we seek to protect through various measures, including confidentiality agreements with licensees, employees, third-party collaborators and consultants who may have had access to such information. If these agreements are breached or our other protective measures should fail, then our contractual or other remedies may not be adequate to cover our losses.

We may also be subject to assertions of intellectual property rights against our medicines by third parties. If successful, these actions may involve payment of future royalties or damages, for example for patent infringement, and may also involve injunctive relief requiring the removal of one or more dosage strengths of a product from the market (or removal of a therapeutic indication from the product’s approved labeling) for a period of time or throughout the life of the asserted intellectual property right. Such damages or such an injunction may have a material impact on our operating income and net sales.

In any given year, we may experience a potentially significant impact on our net sales from products that have already lost intellectual property protections, as

well as products that may lose protection during the year. Because we may have substantially reduced marketing and research and development expenses related to products that are in their final years of exclusivity, the initial loss of protection for a product during a given year could also have an impact on our operating income for that year in an amount corresponding to a significant portion of the product's lost sales. The magnitude of the impact of generic or biosimilar competition on our income could depend on a number of factors. These include, with respect to income in a given year, the time of year at which the generic or biosimilar competitor is launched; the ease or difficulty of manufacturing a competitor product and obtaining regulatory approval to market it; the number of generic or biosimilar competitor products approved, including whether, in the US, a single competitor is granted an exclusive marketing period; whether an authorized generic is launched; the geographies in which generic or biosimilar competitor products are approved, including the strength of the market for generic or biosimilar pharmaceutical products in such geographies, and the comparative profitability of branded pharmaceutical products in such geographies; and our ability to successfully develop and launch new products for patients that may also offset the income lost to generic or biosimilar competition. For more information on the patent and generic competition status of our products, see "Item 4. Information on the Company—Item 4.B Business overview—Intellectual property."

Sandoz spin-off

Risk description
We may not successfully achieve our goals related to our separation from Sandoz and our failure to do so may have an adverse impact on our business

Context and potential impact
We recently completed the separation of Sandoz, our generics and biosimilars division, into a new Swiss publicly traded independent company, by way of a 100% spin-off. In connection with the Sandoz separation, we entered into a separation and distribution agreement and various other agreements. These agreements govern the separation and distribution and the relationship between Novartis and Sandoz going forward, including with respect to the allocation of assets and liabilities between Novartis and Sandoz. The agreements also provide for the performance of services by each company for the benefit of the other company for a period of time. The terms, scope and/or duration of these agreements could negatively impact our ability to pursue other strategic business interests as we will have to devote resources and capacity to fulfilling our obligations that we may prefer to direct elsewhere. If we or Sandoz are unable to satisfy our respective obligations under these agreements, we could incur losses or experience operational challenges or difficulties. These agreements could also lead to disputes over the performance of obligations under these agreements or the allocation of our respective resources. For example, during the term of these agreements, we may have less flexibility to optimize our biologic manufacturing for our own products (or those of other third parties). In addition, pursuant to these agreements, we will perform technical development services for Sandoz, which may involve certain proprietary know-how. While we intend to retain the personnel involved in our technical research and development and to protect our trade secrets, provision of such services might create the incremental potential for the disclosure or misuse of such proprietary know-how, particularly in connection with technology transfer at the end of such arrangements.

Additionally, we may not realize the anticipated strategic, financial, operational, or other benefits from our separation of Sandoz. We cannot predict with certainty when the benefits expected from the Sandoz spin-off will occur or the extent to which they will be achieved. In addition, we incurred one-time costs and may encounter operational inefficiencies in connection with the Sandoz spin-off that may negate some of the benefits we expect to achieve. If we do not realize these assumed benefits, we could suffer a material adverse effect on our financial condition.

Further, if the spin-off does not generally qualify as a tax-neutral transaction for Swiss and U.S. federal income tax purposes, we, our shareholders, or both, could be subject to significant tax liabilities. The spin-off is intended to qualify for tax-neutral treatment for us and our shareholders for Swiss and U.S. federal income tax purposes. If, however, the spin-off fails to qualify as tax-neutral for Swiss and U.S. federal income tax purposes, we, our shareholders, or both, could recognize taxable gain with respect to the spin-off, resulting in Swiss and U.S. income, withholding and capital gains tax consequences. In particular, if the spin-off does not qualify as tax neutral for Swiss and U.S. federal income tax purposes, our shareholders who received shares of Sandoz in the spin-off as part of the separation would be subject to tax as if they had received a taxable distribution equal to the fair market value of such shares. For additional information about the potential tax consequences of the spin-off, see "Item 10.E Taxation—Tax consequences of the Sandoz spin-off."

Environmental, social and governance matters

Risk description
Failure to meet rapidly evolving environmental, social and governance expectations

Context and potential impact
Increasingly, in addition to financial results, companies are being judged by their performance on a variety of environmental, social and governance (ESG) matters, which can contribute to the long-term sustainability of a company's performance. An inability to successfully perform on ESG matters and to meet societal expectations could result in negative impacts on our reputation, recruitment, retention, operations, financial results, and share price.

Topics related to large societal changes such as social inequity, access to medicines and climate change are increasingly important to a wide range of our stakeholders. For example, a variety of organizations measure the performance of companies on ESG topics, and the results of these assessments are widely publicized. In addition, investments in funds that specialize in

companies that perform well in such assessments are increasingly popular, and major institutional investors have publicly emphasized the importance of such ESG measures in making their investment decisions. Our actions related to ESG topics may in the long-term impact our operations and ability to achieve our strategic goals, and ultimately could have a potential negative impact on the value of Novartis.

We actively manage a broad range of ESG matters, taking into consideration their expected impact on the sustainability of our business over time, and the potential impact of our business on society and the environment. We have created a Sustainability & ESG Office, which, in coordination with the ESG Committee of the Executive Committee of Novartis, is tasked with developing our ESG strategy and tracking our performance against our ESG targets. However, considering the fast pace of change of external expectations, and a range of upcoming regulations, there can be no certainty that we will manage such issues successfully, that the ESG standards we currently use to measure our performance against will remain the same, or that we will successfully meet society or investors' expectations. Failure to meet rapidly evolving regulatory requirements and investor and societal expectations could also result in litigation or regulatory actions, which could have a material adverse impact on our reputation, recruitment, retention, operations, financial results, and share price. Additionally, external partners in our value chain that we do not control may not comply with ESG commitments and goals we set for ourselves, which may have a negative impact on our business.

Operational risks

Cybersecurity and data protection

Risk description
Cybersecurity breaches, data loss and catastrophic loss of IT systems

Context and potential impact
We are heavily dependent on critical, complex and interdependent information technology (IT) systems, including internet-based systems to support our business processes. We also outsource significant parts of our IT infrastructure to third-party providers, and currently use these providers to perform business-critical IT services for us. We are therefore vulnerable to cybersecurity attacks and incidents on such networks and systems, whether our own or those of the third-party providers that we contract, and we have experienced, and may in the future experience, such cybersecurity threats and attacks. Cybersecurity threats and attacks take many forms, and the size, age and complexity of our IT systems make them potentially vulnerable to external and internal security threats; outages; malicious intrusions and attacks; cybercrimes, including state-sponsored cybercrimes; malware; misplaced data, lost data or data errors; programming or human errors; or other similar events. The risk of such threats and attacks has increased, as virtual and remote working have become more common, and sensitive data is accessed by employees working in less secure, home-based environments. In addition, due to our reliance on third-party providers, we have experienced, and may in the future experience, interruptions, delays or outages in IT service availability due to a variety of factors outside of our control, including technical failures, natural disasters, fraud, or security attacks experienced by or caused by third-party providers. Interruptions in the service provided by these third parties could affect our ability to perform critical tasks.

A significant information security or other event, such as a disruption or loss of availability of one or more of our IT systems, whether managed by us or a third-party service provider, has previously and could in the future negatively impact important business processes, such as the conduct of scientific research and clinical trials, the submission of data and information to health authorities, our manufacturing and supply chain processes, our shipments to customers, our compliance with legal obligations, and communication between employees and with third parties. IT issues have previously led to, and could in the future lead to, the compromise of trade secrets or other intellectual property that could be sold and used by competitors to accelerate the development or manufacturing of competing products; the compromise of personal financial and health information; and the compromise of IT security data such as usernames, passwords and encryption keys, as well as security strategies and information about network infrastructure, which could allow unauthorized parties to gain access to additional systems or data. In addition, malfunctions in software or medical devices that make significant use of IT could lead to a risk of direct harm to patients.

Although we have experienced some of the events described above, to date they have not had a material impact on our operations. Nonetheless, the occurrence of any of the events described above in the future could disrupt our business operations and result in enforcement actions or liability, including potential government fines and penalties, claims for damages, and shareholder litigation or allegations that the public health, or the health of individuals, has been harmed.

Any significant events of this type could require us to expend significant resources beyond those we already invest to remediate any damage, to further modify or enhance our protective measures, and to enable the continuity of our business.

Strategic technology programs implementation

Risk description
Failure to successfully implement our IT strategy may disrupt our core business processes

Context and potential impact
We rely on various IT systems to operate our complex global business and several of our current IT systems are reaching the end of their useful life, which could cause disruptions to our operational stability. As a result, we are implementing several companywide IT programs to replace and consolidate outdated IT systems and to simplify and standardize our processes, systems and tools, and create a unified data marketplace. Implementation and operation of these new systems involves certain risks, including the potential for a failure of the new

systems to operate as expected; a failure to properly integrate new systems with other systems we use; delays in adopting and scaling of new systems; potential loss of data or information; a failure of, or potential issues with, systems related to our payment and procurement processes; compliance issues; and cost overruns and delays. Our inability to timely and successfully implement our IT strategy may prevent us from materializing the expected business benefits and could lead to business disruptions, cost inefficiencies and potential exposure to legal, regulatory and reputational risks as our internal controls could be negatively affected. Any disruptions or malfunctions of new systems could cause critical information to be delayed, lost, defective, corrupted, or rendered inadequate or inaccessible, which could negatively impact our operations, the effectiveness of our internal controls and financial condition.

Talent management

Risk description
Inability to identify, attract, develop and retain qualified talent for critical roles

Context and potential impact
We rely on identifying, attracting, developing and retaining a diverse, highly skilled workforce across our business and functions to achieve our objectives. If we are unable to sustain our supply of key personnel—including senior members of our scientific and management teams, high-quality researchers and development specialists and skilled employees with key capabilities in key markets—our ability to achieve our major business objectives may be adversely affected. In addition, our brand and reputation could be negatively impacted, and the diversity of our workforce may decline.

The market for skilled talent has become increasingly competitive, and we anticipate this trend will persist in the long term. We face a challenge to attract and retain top talent in several areas, including biology, immunology, chemistry, clinical development, drug manufacturing, data, digital and IT, oncology, and advanced therapy platforms (i.e., gene and cell therapy, radioligand therapy and “xRNA”). In addition, many pharmaceutical and biotechnology companies, universities and research centers, and government entities with significant capital are not only competing with us to attract the same skilled talent but are also aggressively pursuing our experienced talent. Furthermore, if we are unable to retain and engage key talent of companies that we acquire and integrate, we may not be able to realize the full value of these acquisitions.

In recent years, we have adopted new ways of working that include location flexibility and increasingly recruiting from a global pool of talent. However, the success of our business continues to depend on having employees who possess local knowledge of, and experience in, our key markets. The external talent supply is especially limited in many of the geographies that are expected to be sources of growth for us. In the United States, China and several other markets, the geographic mobility of talent is decreasing, as they find ample career opportunities available closer to home.

The risks associated with the challenging talent market will be exacerbated if we are unable to retain and effectively develop employees, and to maintain an internal pipeline with critical skills, experiences, and leadership to deliver our business priorities. As a result, development, engagement, motivation, succession planning and performance rewards for our critical talent are essential to achieve our business priorities.

External partner risk management and human rights

Risk description
Failure to maintain adequate governance and oversight over external partner relationships, and failure of external partners to meet their contractual, regulatory or other obligations

Context and potential impact
We rely on external partners for the performance of certain key business functions and services, including, among others, research and development, manufacturing operations and warehousing and distribution, certain finance functions, sales and marketing activities and data management. Some external partners, particularly those in developing countries, do not have internal compliance systems or resources comparable to ours. As a result, our investment and efforts in relation to external partner management include focusing on risk management and the oversight of such external partners.

Our reliance on external partners poses certain risks, including the misappropriation of our intellectual property, the failure of the external partner to comply with regulatory and quality assurance requirements, the failure of the external partner to comply with environmental, anti-bribery and human rights standards and regulations, unexpected supply disruptions, breach of our agreement by the external partner, and the unexpected termination or nonrenewal of our agreement by the external partner.

In addition, governments require us, and the public expects us, to take responsibility for and report on compliance with various human rights, responsible sourcing and environmental practices, as well as other actions of our external partner contractors around the world.

Ultimately, if external partners fail to meet their obligations to us, we may lose our investment in the relationship with the external partners or fail to receive the expected benefits of our agreements with such external partners. While we aim to identify and assess any risk of harm to society caused by our external partners’ operations, should any of these external partners fail to comply with the law or our standards, or should they otherwise act inappropriately while performing services for us, we could be held responsible for their acts, our reputation may suffer, and penalties could be imposed on us.

Legal, regulatory, ethics and compliance

Risk description
Challenges posed by evolving legal and regulatory requirements, innovative and disruptive technologies, and societal expectations regarding ethical behavior

Context and potential impact

We are subject to an extensive and complex framework of laws and regulations across the jurisdictions in which we operate.

The laws and regulations relevant to the healthcare industry and applicable to us are broad in scope, are subject to change, and have evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our business practices. For example, we have been, are currently, and may in the future be, subject to various significant legal proceedings, such as private party litigation, government investigations and law enforcement actions worldwide. These types of matters may take various forms based on evolving government enforcement and private party litigation priorities, and could include, for example, matters pertaining to: pricing; bribery and corruption; trade regulation and embargo legislation; product liability; commercial disputes; employment and wrongful discharge; antitrust and competition; securities; government benefit programs; reimbursement; rebates; healthcare fraud; sales and marketing practices; insider trading; occupational health and safety; environmental regulations; tax; cyber and data security; use of technologies, including AI; data privacy; regulatory interactions; disclosure compliance; and intellectual property. Such matters can involve civil or criminal proceedings and can retroactively challenge practices previously considered to be legal.

There is also a risk that governance of our medical and patient support activities, and of our interactions with governments, public officials/institutions, healthcare professionals, healthcare organizations and patient organizations may be inadequate or fail, or that we may undertake activities based on improper or inadequate scientific justification.

Legal proceedings and investigations are inherently unpredictable, and significant judgments sometimes occur. Consequently, we may in the future incur judgments that could involve large payments, including the potential repayment of amounts allegedly obtained improperly, and other penalties, including treble damages. In addition, such legal proceedings and investigations, even if meritless, may affect our reputation, may create a risk of potential exclusion from government reimbursement programs in the US and other countries, and may lead to civil litigation or criminal exposure. As a result, having considered all relevant factors, we have in the past and may again in the future enter into major settlements of such claims without bringing them to final legal adjudication by courts or other such bodies, despite having potentially significant defenses against them, to limit the risks they pose to our business and reputation. Such settlements may require us to pay significant sums of money and to enter into corporate integrity or similar agreements, which are intended to regulate company behavior for extended periods. From time to time, we may also initiate challenges to laws or regulations that we believe are illegal or unconstitutional. For example, in September 2023, we filed a lawsuit against the US Department of Health and Human Services and the Centers for Medicare and Medicaid Services because we believe the drug price-setting provisions in the Inflation Reduction Act (IRA) are unconstitutional and will have long-lasting negative consequences for patients by limiting access to medicines now and in the future. The result of this and similar litigation we may pursue in the future is inherently uncertain and may negatively impact our business and reputation.

For information on significant legal matters pending against us, see “Item 18. Financial Statements—Note 21. Provisions and other non-current liabilities” and “Item 18. Financial Statements—Note 29. Commitments and contingent liabilities.”

New requirements may also be imposed on us due to changing government and societal expectations regarding the healthcare industry, and acceptable corporate behavior generally. For example, we are faced with laws and regulations requiring changes in how we do business, including with respect to disclosures concerning our interactions with healthcare professionals, healthcare organizations and patient organizations. These laws and regulations include requirements that we disclose payments or other transfers of value made to healthcare professionals and organizations, as well as information relating to the costs and prices for our products, which represent evolving standards of acceptable corporate behavior. These requirements may cause us to incur significant costs, including substantial time and additional resources, that are necessary to bring our interactions with healthcare professionals and organizations into compliance with these evolving standards.

To support our efforts to comply with the many requirements that impact us, we have a significant global ethics, risk and compliance program in place, and we devote substantial time and resources to efforts to ensure that we conduct business in a lawful manner, and in line with society’s expectations. Despite our efforts, an actual or alleged failure to comply with the law or with heightened public expectations could lead to substantial liabilities that may not be covered by insurance, or to other significant losses.

Manufacturing and product quality

Risk description

Inability to ensure proper controls in product development and product manufacturing, and failure to comply with applicable regulations and standards

Context and potential impact

The development and manufacture of our products is complex and heavily regulated by governmental health authorities around the world. Regardless of whether our products and the related raw materials are developed and manufactured at our own manufacturing sites or by third parties, we must ensure that all development and manufacturing processes comply with regulatory requirements, as well as our own quality standards in order to deliver novel therapies while ensuring patient safety. Failure to comply with regulatory requirements may result in warning letters, suspension of manufacturing, seizure of products, injunctions, product recalls, failure to secure product approvals, debarment or harm to patients or our reputation.

In recent years, global health authorities have substantially intensified their scrutiny of manufacturers’ compliance with regulatory requirements. Any significant

failure by us or our third-party suppliers to comply with regulatory requirements, or with health authorities' expectations, may create the need to suspend clinical trials, shut down production facilities or production lines, and recall commercial products. A failure to fully comply with regulatory requirements could also lead to a delay in the approval of new products, an inability to ship or import our products, and significant penalties and reputational harm.

In addition, the technically complex manufacturing processes required to manufacture many of our products increase the risk of both production failures and product recalls, and can increase the cost of producing our goods. Some of our products require a supply of highly specialized raw materials, such as cell lines, tissue samples, bacteria, viral strains and radioisotopes. In addition, we manufacture and sell a number of sterile products, biologic products and products that involve advanced therapy platforms, such as gene and cell therapy, radioligand therapy, and "xRNA," all of which are particularly complex and involve highly specialized manufacturing technologies. For more information, see "Item 4. Information on the Company—Item 4.B. Business overview—Production." As a result, even slight deviations at any point in their production processes or in the materials used have led to, and may in the future lead to, production failures or recalls.

Supply chain

Risk description
Inability to maintain continuity of product supply

Context and potential impact
Many of our products are produced using technically complex manufacturing processes and require a supply of highly specialized raw materials. For some of our products and raw materials, we may rely on a single source of supply. In addition, we manufacture and sell a number of sterile products, biologic products, and products that involve advanced therapy platforms, such as gene and cell therapy, radioligand therapy, and "xRNA," all of which are particularly complex and involve highly specialized manufacturing technologies. Due to this complexity, there is a risk of production and supply of critical raw materials failures, which may result in supply interruptions or product recalls due to manufactured products not meeting required specifications.

In addition, due to the inherent complexities of our manufacturing processes and the supply chains for advanced therapy platforms, we are required to plan our production activities and purchase of materials well in advance. If we suffer from third-party raw material shortages, underestimate market demand for a product, or fail to accurately predict when a new product will be approved for sale, then we may not be able to produce sufficient product to meet demand. These issues could be made worse during a pandemic, or geopolitical events, such as wars in certain parts of the world, and could lead to (i) a sudden increase in demand for selected medicinal products, resulting in the short-term unavailability of critical materials; (ii) logistical and supply challenges that may lead to our inability to ship products from one location to another due to restrictions imposed as a result of a pandemic or geopolitical events and any related sanctions, which can also impact transportation and warehousing costs; or (iii) our inability to properly operate a manufacturing site due to restrictions imposed as the result of a pandemic or any issues arising from geopolitical events.

Our or our suppliers' inability to manage such issues could lead to shutdowns, product shortages, or to us being entirely unable to supply products to patients for an extended period of time. Furthermore, as our products are intended to promote the health of patients, such shortages or shutdowns could endanger our reputation and have led to, and could continue to lead to, significant losses of sales revenue, potential litigation or allegations that the public health, or the health of individuals, has been harmed.

Data privacy

Risk description
Noncompliance with personal data protection laws and regulations

Context and potential impact
We operate in an environment that relies on the collection, processing, analysis and interpretation of large sets of patients and other individuals' personal information, including via social media and mobile technologies. In addition, the operation of our business requires data to flow across the borders of numerous countries in which there are different, potentially conflicting, and frequently changing, data privacy laws in effect. Examples of such laws include: the EU General Data Protection Regulation (GDPR); the California Consumer Privacy Act; Brazil's General Personal Data Protection Law; and the Personal Information Protection Law in China. Such laws impose stringent requirements on how we and third parties with whom we contract collect, share, export or otherwise process personal information, and provide for significant penalties for noncompliance. Breaches of our systems or those of our third-party contractors, or other failures to protect the data we collect from misuse or breach by third parties, could expose such personal information to unauthorized persons.

Events involving the substantial loss of personal information, use of personal information without a legal basis, or other privacy violations could give rise to significant liability, reputational harm, damaged relationships with business partners, and potentially substantial monetary penalties and other sanctions under laws enacted or being enacted around the world. Such events could also lead to restrictions on our ability to use personal information and/or transfer personal information across country borders, which could interfere with critical business operations. In addition, there is a trend of increasing divergence of data privacy legal frameworks, not only across these frameworks but also within individual legal frameworks themselves. This divergence may constrain the implementation of global business processes and may lead to different approaches on the use of health data for scientific research, which may have a negative impact on our business and operations.

Falsified medicines

Risk description
Impact of falsified medicines on patient safety, and reputational and financial harm to Novartis and our products

Context and potential impact
We continue to be challenged by the vulnerability of distribution channels to falsified medicines, which include counterfeit, stolen, tampered and illegally diverted medicines, as defined by the World Health Organization.

Falsified medicines pose patient safety risks and can be seriously harmful or life-threatening. Reports of adverse events related to falsified medicines and increased levels of falsified medicines in the healthcare system affect patient confidence in genuine medicines and in healthcare systems in general. These events could also cause us substantial reputational and financial harm, and potentially lead to litigation if the adverse event from the falsified medicine is mistakenly attributed to the genuine one. Stolen or illegally diverted medicines that are not properly stored and later sold through unauthorized channels could adversely impact patient safety, our reputation and our business. Furthermore, there is a direct financial loss when falsified medicines replace sales of genuine medicines, or genuine medicines are recalled following the discovery of falsified products.

Emerging risks

Geopolitical developments

Risk description
Impact of geo- and socio-political threats

Context and potential impact
Geopolitical tensions in various parts of the world worsened in 2023 and could continue to worsen in 2024 and beyond. Direct conflicts, including the ongoing wars in Ukraine and the Middle East, an increasingly challenging economic landscape and social unrest, each have both a direct and indirect impact on the pharmaceutical industry and lead to a degree of uncertainty about the future.

As a result of ongoing geopolitical tensions, certain countries have adopted, and may in the future adopt additional, protectionist measures including the imposition of tariffs. Tariffs that are intended to shield domestic markets from foreign competition and the possibility of additional trade restrictions, such as export controls, could have a material impact on our business. If tariffs or export controls on pharmaceutical products or active pharmaceutical ingredients (APIs) were increased in certain parts of the world, our supply chain and flow of our products could be immediately disrupted. There is also an additional risk that aggressive monetary and fiscal policies by governments and central banks to curb inflation may prompt market-specific recessions and raise the cost-of-living, further putting pressure on pricing and cost containment for the pharmaceutical industry.

Collectively, unstable geo- and socio-political conditions could, among other things, disturb the international flow of goods and increase the costs and difficulties of international transactions. This could potentially impact our ability to develop and supply our products to patients in an undisrupted fashion, and further erode reimbursement mechanisms for our medicines.

Macroeconomic developments

Risk description
Impact of macroeconomic developments

Context and potential impact
Our business may be impacted by deteriorating macroeconomic and financial conditions directly affecting us, our suppliers, payers and consumers. Given that patients, in many countries, directly pay a sizable and increasing portion of their own healthcare costs, there is a risk that consumers may cut back on prescription drugs due to financial constraints.

Negative macroeconomic developments may also adversely affect the ability of payers, as well as our distributors, customers, suppliers, and service providers, to pay for our products, or to buy necessary inventory or raw materials, and to perform their obligations under agreements with us. Weakening growth and rising interest rates may also increase the credit risk of our counterparties. Although we make efforts to monitor the financial condition and liquidity of these third parties, our ability to do so is limited, and some of them may become unable to pay their bills in a timely manner or may even become insolvent. These risks may be elevated with respect to our interactions with fiscally challenged government payers, or with third parties with substantial exposure to such payers.

At the same time, significant changes, and potential future volatility in financial markets, the consumer and business environment, the competitive landscape, and the global political and security landscape make it increasingly difficult for us to predict our revenues and earnings. As a result, any revenue or earnings guidance or outlook that we have given or might give may be overtaken by events or may otherwise prove to be inaccurate. Although we endeavor to give reasonable estimates of future revenues and earnings at the time at which we give such guidance, based on then-current knowledge and conditions, there is a risk that such guidance or outlook will prove to be incorrect.

Asset price corrections in financial markets may also result in lower returns on our financial investments. In addition, pricing pressures in developed markets resulting from efforts to reduce the cost of healthcare (e.g., the Inflation Reduction Act in the US, which targets drug prices) may have a negative impact on our revenue and our net sales. In addition, inflation may have an impact on our operating costs in the form of higher prices for supplies, energy, raw materials, wages, and capital, which could reduce our net income.

Uncertainties around future central bank and other economic policies in the US and EU, including rising interest rates, as well as high debt levels in some countries could also impact world trade. Sudden increases in economic, currency or financial market volatility in different countries, such as appreciation of the US dollar, have also impacted, and may continue to have an unpredictable impact on our business, or results of operations,

including the conversion of our operating results into our reporting currency, the US dollar, as well as the value of our investments in our pension plans.

For more information about the effect of price controls on our business, see “Item 4. Information on the Company—Item 4.B—Business overview—Price controls.” See also “Item 5. Operating and Financial Review and Prospects—Item 5.B Liquidity and capital resources—Effects of currency fluctuations,” “Item 5. Operating and Financial Review and Prospects—Item 5.B Liquidity and capital resources—Condensed consolidated balance sheets,” “Item 18. Financial Statements—Note 16. Trade receivables” and “Item 18. Financial Statements—Note 30. Financial instruments – additional disclosures.”

Climate change

Risk description
Failure to manage physical and transition risks from climate change

Context and potential impact
We are exposed to a broad range of climate risks such as transition risks (e.g., regulatory frameworks, carbon pricing, and the cost of and access to capital) and physical risks (e.g., heat, water scarcity, rising sea levels, and flooding from severe weather events), which could vary in magnitude and impact across different countries.

Climate change has triggered, and may continue to trigger, the adoption of new regulatory requirements across the globe, as well as rapidly evolving societal expectations. To comply with such legislation and meet such expectations, we may be required to increase our investment in technology to reduce our energy use, water use and greenhouse gas emissions. In addition, legislative and regulatory action, both current and in the future, includes or could include, carbon pricing, climate risk-related disclosures, and changes in zoning or building codes to increase climate resilience. As a result, the combined impact of these transition risks could increase our direct operating costs or be passed on to us through the impact on our supply chain. As a result of these transition risks, we are committed to becoming carbon neutral in our own operations by 2025, and carbon neutral across our value chain by 2030. In addition, we are committed to achieving net zero across our value chain by 2040. Any failure to achieve these commitments in the expected time frame, or at all, could result in negative impacts on our reputation, our operations, and the price of our shares.

Climate change has created, and will continue to create, physical risks to our business. Some of our production facilities that depend on the availability of significant water supplies are located in areas where fresh water is increasingly scarce. Other facilities are located in areas that, due to increasingly violent weather events, rising sea levels, or both, are increasingly at risk of substantial damage. In regions where such a risk is present, this has an impact not only on our own operations but also our distributed supply chain. Such events may result in the loss of life, increased costs, business interruptions, destruction of facilities, and disruption to healthcare systems that patients use to access our medicines.

Tax laws and developments

Risk description
Changes in tax laws or their application

Context and potential impact
Our multinational operations are taxed under the laws of the countries and other jurisdictions in which we operate. Changes in tax laws or in their application could lead to an increased risk of international tax disputes and an increase in our effective tax rate, which could adversely affect our financial results. The integrated nature of our worldwide operations can produce conflicting claims from revenue authorities in different countries as to the profits to be taxed in the individual countries, including potential disputes relating to the prices our subsidiaries charge one another for intercompany transactions, known as transfer pricing. Most of the jurisdictions in which we operate have double tax treaties with other foreign jurisdictions, which provide a framework for mitigating the impact of double taxation on our revenues and capital gains. However, mechanisms developed to resolve such conflicting claims are largely untried and can be expected to be very lengthy. Accruals for tax contingencies are made based on experience, interpretations of tax law, and judgments about potential actions by tax authorities. However, due to the complexity of tax contingencies, the ultimate resolution of any tax matter may result in payments materially different from the amounts accrued.

In 2019, the Organization for Economic Co-operation and Development (OECD) launched a new initiative on behalf of the G20 to minimize profit shifting by working toward a global tax framework that ensures that corporate income taxes are paid where consumption takes place, in addition to introducing a global standard on minimum taxation combined with new tax dispute resolution processes. This project achieved OECD political consensus in October 2021, and the detailed principles are still under discussion by the OECD and political leaders. The OECD expects that the implementation of these new principles will begin globally in 2024. However, some countries already announced postponement to 2025 while others have not taken any implementation steps so far. Once changes to the tax laws in any jurisdiction in which we operate are enacted or substantially enacted, we will be subject to the OECD top-up tax, the aim of which is to bring the total amount of taxes paid on our profit in a given jurisdiction up to a minimum rate of 15%. In June 2023, the Swiss public voted to approve an amendment to the Swiss Constitution that provides the legal basis for the implementation of an OECD compliant minimum tax in Switzerland. In December 2023, the Swiss federal council partially implemented the OECD 15% minimum tax for the financial year 2024 in the form of a qualified domestic top-up tax (QDMTT), which will be assessed on certain qualifying profits earned by companies domiciled in Switzerland. This QDMTT will not be applied to qualifying profits earned by a company’s affiliates domiciled in tax jurisdictions outside of Switzerland. The timing and specific provisions of any further tax regulations remain subject to assessments in political and technical forums at both a federal and cantonal level.

Due to the ongoing discussion in many countries on the implementation and additional guidance from the OECD, the full impact of the OECD minimum tax project on our financial position, income statement and cash flows cannot currently be estimated. On September 12, 2023, the EU Commission published two draft directives relating to international tax. The draft Business in Europe: Framework for Income Taxation (BEFIT) directive provides common rules for determining the corporate tax base for EU-based entities that are part of a group with global consolidated revenues above EUR 750 million. The BEFIT proposal includes provisions for a formula-driven allocation of profits between relevant EU member states which would then be subject to the corporate income tax rate of the respective member state. The draft transfer pricing directive aims to harmonize transfer pricing rules within the EU consistent with the OECD Transfer Pricing Guidelines. It also clarifies processes for relieving double taxation within the EU. Both draft directives require unanimous agreement among EU member states before they can be further implemented. In the US, the IRA was signed into law on August 16, 2022. The IRA creates a 15% corporate alternative minimum tax on the profits of corporations whose average annual adjusted financial statement income exceeds USD 1.0 billion. The IRA also includes a one percent excise tax on certain corporate stock repurchases. Additionally, the IRA also contains provisions that affect tax-exempt entities, including tax credit opportunities to encourage investment in clean energy and expanded incentives for energy-efficient construction by tax-exempt entities.

While we have taken steps to comply with the evolving tax initiatives of the OECD, the US and the EU, and we will continue to do so, significant uncertainties remain as to the outcome of our efforts.

For more information, see “Item 18. Financial Statements—Note 7. Income taxes” and “Item 18. Financial Statements—Note 13. Deferred tax assets and liabilities.”

General risks

Indebtedness

Risk description
Our indebtedness could adversely affect our operations

Context and potential impact
As of December 31, 2023, we had USD 18.4 billion of non-current financial debt, and USD 6.2 billion of current financial debt. Our current and long-term debt requires us to dedicate a portion of our cash flow to service interest and principal payments and, if interest rates rise, this amount may increase. As a result, our existing debt may limit our ability to use our cash flow to fund capital expenditures, to engage in transactions, or to meet other capital needs, or otherwise may place us at a competitive disadvantage relative to competitors that have less debt. Our debt could also limit our flexibility to plan for and react to changes in our business or industry, and increase our vulnerability to general adverse economic and industry conditions, including changes in interest rates or a downturn in our business or the economy. We may also have difficulty refinancing our existing debt or incurring new debt on terms that we would consider to be commercially reasonable, if at all.

Goodwill and intangible assets

Risk description
Goodwill and intangible assets resulting in significant impairment charges

Context and potential impact
We carry a significant amount of goodwill and other intangible assets on our consolidated balance sheet, including, in particular, substantial goodwill and other intangible assets obtained through acquisitions, including most recently through our acquisitions of The Medicines Company, Endocyte, Novartis Gene Therapies, ADACAP, and Chinook Therapeutics. As a result, we may incur significant impairment charges in the future if the fair value of the intangible assets and the groupings of cash-generating units containing goodwill would be less than their carrying value on our consolidated balance sheet at any point in time.

We regularly review our intangible and tangible assets for impairment, including identifiable intangible assets and goodwill. Any significant impairment charges could have a material adverse effect on our results of operations and financial condition. In 2023, for example, we recorded intangible asset impairment charges of USD 3.0 billion.

For a detailed discussion about how we determine whether an impairment has occurred, what factors could result in an impairment, and the impact of impairment charges on our results of operations, see Item 18. Financial Statements—Note 1. Accounting policies” and “Item 18. Financial Statements—Note 12. Goodwill and intangible assets.”

Foreign currency exchange rates

Risk description
Negative effect on financial results due to foreign currency exchange rate fluctuations

Context and potential impact
Changes in exchange rates between the US dollar, which is our reporting currency, and other currencies can result in significant increases or decreases in our reported sales, costs and earnings as expressed in US dollars, and in the reported value of our assets, liabilities and cash flows.

In addition to ordinary market risk, there is a risk that countries could take affirmative steps that could significantly impact the value of their currencies. Such steps could include “quantitative easing” measures and potential withdrawals by countries from common currencies. In addition, countries facing local financial difficulties, including countries experiencing high inflation rates, and highly indebted countries facing large capital outflows, may impose controls on the exchange of foreign currency. Currency exchange controls and sanctions could limit our ability to distribute retained earnings from our local affiliates, or to pay intercompany payables due from those countries.

Despite measures undertaken to reduce or hedge against foreign currency exchange risks, as a significant portion of our earnings and expenditures are in currencies other than the US dollar, including expenditures in Swiss francs that are significantly higher than our revenue in Swiss francs, any such exchange rate volatility may negatively and materially impact our results of operations and financial condition, and may impact the reported value of our net sales, earnings, assets and liabilities. In addition, the timing and extent of such volatility can be difficult to predict. Furthermore, depending on the movements of particular foreign exchange rates, we may be materially adversely affected at a time when the same currency movements are benefiting some of our competitors.

For more information on the effects of currency fluctuations on our consolidated financial statements and on how we manage currency risk, see "Item 5. Operating and Financial Review and Prospects—Item 5.B Liquidity and capital resources—Effects of currency fluctuations" and "Item 18. Financial Statements—Note 30. Financial instruments – additional disclosures."

Key customers

Risk description
Concentration among our key customers

Context and potential impact
A significant portion of our global sales is made to a relatively small number of drug wholesalers, retail chains and other purchasing organizations. For example, our three most important customers globally accounted for approximately 15%, 13% and 8%, respectively, of net sales from continuing operations in 2023. The largest trade receivables outstanding were for these three customers, amounting to 17%, 13% and 8%, respectively, of the trade receivables at December 31, 2023. Historically, there has been a trend of consolidation among our customer base, which may continue in the future. As a result, we are exposed to a concentration of credit risk among our key customers. If one or more of our major customers experienced financial difficulties, the effect on us would be considerable, and could include a substantial loss of sales and an inability to collect amounts owed to us.

Environmental matters

Risk description
Impact of environmental liabilities

Context and potential impact
The environmental laws of various jurisdictions impose actual and potential obligations on us to investigate and remediate contaminated sites, including in connection with activities in the past by businesses that are no longer part of Novartis. In some cases, these remediation efforts may take many years. While we have set aside provisions for known worldwide environmental liabilities that are probable and estimable, there is no guarantee that additional costs will not be incurred beyond the amounts for which we have provided in our consolidated financial statements. If environmental contamination resulting from our facility operations, business activities or products adversely impacts third parties or if we fail to properly manage the safety of our facilities, including the safety of our employees and contractors, and the environmental risks, we may face substantial one-time and recurring costs and other penalties, and be required to increase our provisions for environmental liabilities. Furthermore, our headquarters and a number of our major production and research facilities are located near earthquake fault lines in Basel, Switzerland. Other major facilities are located near major earthquake fault lines in various locations around the world. A major earthquake could result in loss of life, business interruptions and the destruction of our facilities. See also "Item 4. Information on the Company—Item 4.D Property, plants and equipment" and "Item 18. Financial Statements—Note 21. Provisions and other non-current liabilities."

Pension plans

Risk description
Inaccuracies in the assumptions and estimates used to calculate our pension plan and other post-employment obligations

Context and potential impact
We sponsor pension and other post-employment benefit plans in various forms that cover a significant portion of our current and former employees. For post-employment plans with defined benefit obligations, we are required to make significant assumptions and estimates about future events in calculating the expense and the present value of the liability related to these plans. These include assumptions about the discount rates we apply to estimate future defined benefit obligations and net periodic pension expense, as well as rates of future pension increases. In addition, our actuarial consultants provide our management with historical statistical information, such as withdrawal and mortality rates in connection with these estimates.

Assumptions and estimates that we use may differ materially from the actual results we experience due to changing market and economic conditions, higher or lower withdrawal rates, and longer or shorter life spans of participants, among other factors. Depending on events, such differences could have a material effect on our total equity, and may require us to make additional contributions to our pension funds.

For more information on obligations under retirement and other post-employment benefit plans and underlying actuarial assumptions, see "Item 18. Financial Statements—Note 26. Post-employment benefits for employees."