

Risk Factors Comparison 2025-02-14 to 2024-02-20 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text Section**

You should carefully consider the following risks and other information in this Form 10-K in evaluating AbbVie and AbbVie's common stock. Any of the following risks could materially and adversely affect AbbVie's results of operations, financial condition or cash flows. The risk factors generally have been separated into two groups: risks related to AbbVie's business and risks related to AbbVie's common stock. Based on the information currently known to it, AbbVie believes that the following information identifies the most significant risk factors affecting it in each of these categories of risks. However, the risks and uncertainties AbbVie faces are not limited to those set forth in the risk factors described below and may not be in order of importance or probability of occurrence. Additional risks and uncertainties not presently known to AbbVie or that AbbVie currently believes to be immaterial may also adversely affect its business. In addition, past financial performance may not be a reliable indicator of future performance and historical trends should not be used to anticipate results or trends in future periods. If any of the following risks and uncertainties develops into actual events, these events could have a material adverse effect on AbbVie's business, results of operations, financial condition or cash flows. In such case, the trading price of AbbVie's common stock could decline.

Risks Related to AbbVie's Business

The expiration or loss of patent protection and licenses, including the loss of exclusivity for ~~Humira~~ **any of our products** and increased competition from **generics and** biosimilars, may adversely affect AbbVie's revenues and operating earnings. AbbVie relies on patent, trademark and other intellectual property protection in the discovery, development, manufacturing and sale of its products. In particular, patent protection is, in the aggregate, important in AbbVie's marketing of pharmaceutical products in the United States and most major markets outside of the United States. Patents covering AbbVie products normally provide market exclusivity, which is important for the profitability of many of AbbVie's products. As patents for certain of its products expire, AbbVie could face competition from lower priced generic or biosimilar products. The expiration or loss of patent protection for a product typically is followed promptly by substitutes that may significantly reduce sales for that product in a short amount of time. If AbbVie's competitive position is compromised because of generics, biosimilars or otherwise, it could have a material adverse effect on AbbVie's business and results of operations. In addition, proposals emerge from time to time for legislation to further encourage the early and rapid approval of generic drugs or biosimilars. Any such proposals that are enacted into law could increase the impact of generic **or biosimilar** competition. Large pharmaceutical companies and generics manufacturers of pharmaceutical products continue to expand into the biotechnology field and form partnerships to pursue biosimilars. Companies have developed and are developing biosimilars that compete with AbbVie's biologic products, ~~including Humira~~. As competitors obtain marketing approval for biosimilars referencing AbbVie's biologic products, AbbVie's products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Expiration of or successful challenges to AbbVie's applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired. As a result, AbbVie could face increased litigation and administrative proceedings with respect to the validity and / or scope of patents relating to its biologic products. **For example, a significant portion of AbbVie's revenues and operating earnings are derived from several major products. Specifically, Skyrizi, Humira and Rinvoq each represented greater than 10 % of AbbVie's total net revenues and, in aggregate, these products** accounted for approximately ~~27-47~~ **27-47** % of AbbVie's total net revenues in ~~2023-2024~~. ~~Humira is facing~~ **has faced** competition from biosimilar products in the United States following the loss of exclusivity in 2023, ~~which~~ **AbbVie anticipates such loss** will continue to cause a significant decline in Humira's revenue and could adversely affect AbbVie's revenues and operating earnings. **AbbVie's principal patents and trademarks are described in greater detail in Item 1, "Business — Intellectual Property Protection and Regulatory Exclusivity" and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations — Results of Operations," and litigation regarding these patents is described in Item 3, "Legal Proceedings."** ~~2023-2024~~ Form 10-K | 14 ~~AbbVie's principal patents and trademarks are described in greater detail in Item 1, "Business — Intellectual Property Protection and Regulatory Exclusivity" and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations — Results of Operations," and litigation regarding these patents is described in Item 3, "Legal Proceedings."~~

AbbVie's major products could lose patent protection earlier than expected, which could adversely affect AbbVie's revenues and operating earnings. ~~A significant portion of AbbVie's revenue and operating earnings are derived from several major products.~~ Third parties or government authorities may challenge or seek to invalidate or circumvent AbbVie's patents and patent applications. For example, manufacturers of generic pharmaceutical products file, and may continue to file, Abbreviated New Drug Applications with the FDA seeking to market generic forms of AbbVie's products prior to the expiration of relevant patents owned or licensed by AbbVie by asserting that the patents are invalid, unenforceable and / or not infringed. In addition, petitioners have filed, and may continue to file, challenges to the validity of AbbVie's patents under the 2011 Leahy-Smith America Invents Act, which created inter partes review and post grant review procedures for challenging patent validity in administrative proceedings at the United States Patent and Trademark Office. Although most of the challenges to AbbVie's intellectual property have come from other businesses, governments **may have and are expected to** also challenge intellectual property rights. For example, court decisions and potential legislation relating to patents, such as legislation regarding biosimilars, and other regulatory initiatives may result in further erosion of intellectual property protection. In addition, certain governments outside the United States have indicated that compulsory licenses to patents may be sought to further their domestic policies or on the basis of national emergencies, such as HIV / AIDS. If triggered, compulsory licenses may diminish or eliminate sales and profits from those jurisdictions and negatively affect AbbVie's results of operations. AbbVie normally

responds to challenges by vigorously defending its patents, including by filing patent infringement lawsuits. Patent litigation, administrative proceedings and other challenges to AbbVie's patents are costly and unpredictable and may deprive AbbVie of market exclusivity for a patented product. To the extent AbbVie's intellectual property is successfully challenged, circumvented or weakened, or to the extent such intellectual property does not allow AbbVie to compete effectively, AbbVie's business will suffer. To the extent that countries do not enforce AbbVie's intellectual property rights or require compulsory licensing of AbbVie's intellectual property, AbbVie's revenues and operating earnings will be reduced. A third party's intellectual property may prevent AbbVie from selling its products or have a material adverse effect on AbbVie's profitability and financial condition. Third parties may claim that an AbbVie product infringes upon their intellectual property. In addition, in its pursuit of valid business opportunities, AbbVie may be required to challenge intellectual property rights held by others that it believes were improperly granted. Resolving an intellectual property infringement or other claim can be costly and time consuming and may require AbbVie to enter into license agreements. AbbVie cannot guarantee that it would be able to obtain license agreements on commercially reasonable terms. A successful claim of patent or other intellectual property infringement could subject AbbVie to significant damages or an injunction preventing the manufacture, sale, or use of the affected AbbVie product or products. Any of these events could have a material adverse effect on AbbVie's profitability and financial condition. AbbVie's research and development efforts may not succeed in developing ~~and marketing commercially successful~~ **products and technologies that can be successfully commercialized**, which may cause its revenues and profitability to decline. To remain competitive, AbbVie must continue to launch new products and new indications and / or brand extensions for existing products. Such launches must generate revenue sufficient both to cover its substantial research and development costs and to replace revenues of profitable products that are lost to or displaced by competing products or therapies. Failure to do so would have a material adverse effect on AbbVie's revenue and profitability. Accordingly, AbbVie commits substantial effort, funds and other resources to research and development and must make ongoing substantial expenditures without any assurance that its efforts will be commercially successful. A high rate of failure in the biopharmaceutical industry is inherent in the research and development of new products, and failure can occur at any point in the research and development process, including after significant ~~funds~~ **resources** have been invested. Products that appear promising in development may fail to reach the market for numerous reasons, including failure to demonstrate effectiveness, safety concerns, superior safety or efficacy of competing therapies, failure to achieve positive clinical or pre-clinical outcomes beyond the current standards of care, inability to obtain necessary regulatory approvals or delays in the approval of new products and new indications, limited scope of approved uses, excessive costs to manufacture or the failure to obtain or maintain intellectual property rights, or infringement of the intellectual property rights of others. ~~15 | 2023 Form 10-K~~ Decisions about research studies made early in the development process of a pharmaceutical product candidate can affect the marketing strategy once such candidate receives **regulatory** approval. More detailed studies may demonstrate additional benefits that can help in the marketing, but they also consume time and resources and may delay submitting the pharmaceutical product candidate for regulatory approval. AbbVie cannot guarantee that a proper balance of speed and testing will be made with respect to each pharmaceutical product candidate or that decisions in this area would not adversely affect AbbVie's results of operations. **15 | 2024 Form 10-K** Even if AbbVie successfully develops and markets new products or enhancements to its existing products, they may be quickly rendered obsolete by changing clinical preferences, changing industry standards, or competitors' innovations. AbbVie's innovations may not be accepted quickly in the marketplace because of existing clinical practices or uncertainty over third-party reimbursement. AbbVie cannot state with certainty when or whether any of its products under development will be launched, whether it will be able to develop, license, or otherwise acquire compounds or products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause AbbVie's products to become obsolete, causing AbbVie's revenues and operating results to suffer. AbbVie is subject to cost-containment efforts and pricing pressures that could cause a reduction in revenues and operating earnings, and changes in the terms of rebate and chargeback programs, which are common in the pharmaceuticals industry, could have a material adverse effect on AbbVie's operations. Cost-containment efforts by governments and private organizations are described in greater detail in Item 1, "Business — Regulation — Commercialization, Distribution and Manufacturing." To the extent these cost containment efforts are not offset by greater demand, increased patient access to health care, or other factors, AbbVie's revenues and operating earnings will be reduced. In the United States, ~~the~~ **European Union member states** and other countries, AbbVie's business has experienced downward pressure on product pricing, and this pressure could increase in the future. AbbVie is subject to increasing public and legislative pressure with respect to pharmaceutical pricing. In the United States, practices of managed care groups, and institutional and governmental purchasers, as well as federal laws and regulations related to Medicare and Medicaid, contribute to pricing pressures. In particular, the IRA will have the effect of reducing prices and reimbursements for certain of our products, which could significantly impact AbbVie's results of operations. Under the IRA, the U. S Department of Health and Human Services can effectively set prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D. Generally, these government prices can apply as soon as nine years (for small-molecule drugs) or 13 years (for biological products) from their FDA approval and will be capped at a statutory ceiling price that is likely to represent a significant discount from average prices to wholesalers and direct purchasers. In August 2023, ~~HHS the U. S. Department of Health and Human Services~~, through the CMS, selected Imbruvica as one of the first 10 medicines subject to government-set prices beginning in 2026. ~~In The price-setting process will conclude by August 1, 2024, and on September 1, 2024, the CMS will publish~~ **published Medicare Part D** prices that will be applicable to ~~the~~ **these medicines, including Imbruvica, 10 drugs in the Medicare program** beginning January 1, 2026. ~~In January 2025, HHS, through the CMS, selected Vraylar and Linzess as~~ **two of the 15 medicines subject to government-set prices in Medicare Part D beginning in 2027**. It is possible that more of our products, including products that generate substantial revenues, could be selected in future years, which could, among other things, accelerate revenue erosion prior to expiration of intellectual property protections. In addition, beginning in January 2025,

under the IRA, the 70 % coverage gap discount program **was** will be replaced by a 10 % manufacturer discount for all Medicare Part D beneficiaries that have met their deductible and incurred out of pocket drug costs below a \$ 2, 000 threshold and a 20 % discount for beneficiaries that have incurred out of pocket drug costs above the \$ 2, 000 threshold under the new Part D benefit redesign. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties, which could be significant. The IRA has and will continue to meaningfully impact AbbVie' s business strategies and those of others in the pharmaceutical industry. The full impact of the IRA on AbbVie' s business and the pharmaceutical industry, including the implications to us of our or a competitor' s product being selected for price setting, remains uncertain. AbbVie continues to evaluate the impact that the IRA may have on the company. The potential for continuing changes to the health care system in the United States and the increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid and private sector beneficiaries may result in additional pricing pressures. ~~Additionally, changes to U. S. tax laws now require (i) a 15 % alternative minimum tax generally applied to U. S. corporations on adjusted financial statement income beginning in 2023 and (ii) a non- deductible 1 % excise tax provision on net stock repurchases.~~ In major markets worldwide, governments play a significant role in funding health care services and determining the pricing and reimbursement of pharmaceutical products. Consequently, in those markets, AbbVie is subject to government decision- making and budgetary actions with respect to its products. In particular, many European countries have ongoing government- mandated price reductions for many pharmaceutical products, and AbbVie anticipates continuing pricing pressures in Europe. Differences between countries' pricing regulations could lead to third- party cross- border trading in AbbVie' s products that results in a reduction in revenues and operating earnings. Rebates related to government programs, such as fee- for- service Medicaid or Medicaid managed care programs, arise from laws and regulations. AbbVie cannot predict with certainty if additional government initiatives to contain health care ~~2023 Form 10- K | 16~~ costs or other factors could lead to new or modified regulatory requirements that include higher or incremental rebates or discounts. Other rebate and discount programs arise from contractual agreements with private payers. Various factors, including market factors and the ability of private payers to control patient access to products, may provide payers the leverage to negotiate higher or additional rebates or discounts that could have a material adverse effect on AbbVie' s operations. **2024 Form 10- K | 16** A portion of AbbVie' s near- term pharmaceutical pipeline relies on collaborations with third parties, which may adversely affect the development and sale of its products. AbbVie depends on alliances and joint ventures with pharmaceutical and biotechnology companies for a portion of the products in its near- term pharmaceutical pipeline. Failures by these parties to meet their contractual, regulatory, or other obligations to AbbVie, or any disruption in the relationships between AbbVie and these third parties, could have an adverse effect on AbbVie' s pharmaceutical pipeline and business. In addition, AbbVie' s collaborative relationships for research and development extend for many years and may give rise to disputes regarding the relative rights, obligations and revenues of AbbVie and its collaboration partners, including the ownership of intellectual property and associated rights and obligations. **This Such disputes** could result in ~~the AbbVie' s~~ loss of intellectual property rights or protection, delay the development and sale of potential pharmaceutical products, affect the effective sale and delivery of AbbVie' s commercialized products and lead to lengthy and expensive litigation, administrative proceedings or arbitration. Biologics carry unique risks and uncertainties, which could have a negative impact on AbbVie' s business and results of operations. The successful discovery, development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and current governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. As a result, manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture and sell biologics — including Humira, Skyrizi ~~and~~, Botox **and Creon** — could have a negative impact on AbbVie' s business and results of operations. New products and technological advances by AbbVie' s competitors may negatively affect AbbVie' s results of operations. AbbVie competes with other research- based pharmaceutical and biotechnology companies that research, develop, manufacture, market and sell proprietary pharmaceutical products and biologics. ~~For example, Humira competes with anti- TNF products and other competitive products intended to treat a number of disease states and Mavyret / Maviret competes with other available hepatitis C treatment options. In addition, in the past few years, a number of other companies have started to develop, have successfully developed and / or are currently marketing products that are being positioned as competitors to Botox.~~ All of these competitors may introduce new products or develop technological advances that compete with AbbVie' s products in therapeutic areas such as immunology, oncology, aesthetics, neuroscience and eye care. In addition, as AbbVie products lose exclusivity, competition surrounding such products will increase and generic and biosimilar products will increasingly penetrate the markets. **Furthermore, consolidation among certain pharmaceutical and biotechnology companies can enhance such advantages. These advantages may make it difficult for us to compete with them successfully to discover, develop and market new products and for our current products to compete with new products or indications they may bring to market.** AbbVie cannot predict with certainty the timing or impact of the introduction by competitors of new products or technological advances. Such competing products may be safer, more effective, more effectively marketed or sold, have lower prices or better insurance coverage or reimbursement levels, or have superior performance features than AbbVie' s products, and this may negatively impact AbbVie' s business and results of operations. The manufacture of many of AbbVie' s products is a highly exacting and complex process **requiring critical environmental controls**, and if AbbVie or one of its suppliers encounters problems manufacturing AbbVie' s products, AbbVie' s business could suffer. The manufacture of many of AbbVie' s products is a highly exacting and complex process, due

in part to strict regulatory requirements. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for AbbVie's products, changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, **labor shortages, supply chain disruption, pandemics**, man-made or natural disasters and environmental factors. If problems arise during the production of a batch of product, such batch of product may have to be ~~17 | 2023 Form 10-K~~ discarded and AbbVie may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relations, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred. **17 | 2024 Form 10-K** AbbVie uses raw materials and components in its pharmaceutical and biologic manufacturing processes, including those sourced from single suppliers **around the world**, and an interruption in the supply of those raw materials and components could adversely affect AbbVie's business and results of operations. AbbVie uses raw materials and components in its pharmaceutical and biologic manufacturing processes that may be sourced from single suppliers. The failure of AbbVie's suppliers, and particularly its single-source suppliers, to fulfill their contractual obligations in a timely manner or as a result of regulatory noncompliance or physical disruption at a manufacturing site may impair AbbVie's ability to deliver its products to customers on a timely and competitive basis, which could adversely affect AbbVie's business and results of operations. Increases in demand on any of AbbVie's suppliers could result in delays and disruptions in the manufacturing, distribution and sale of its products and / or product shortages, leading to lost revenue. Finding an alternative supplier could take a significant amount of time and involve significant expense due to the nature of the products and the need to obtain regulatory approvals. AbbVie cannot guarantee that it will be able to reach agreement with alternative providers or that regulatory authorities would approve AbbVie's use of such alternatives. Business interruption insurance may not provide adequate compensation in the case of a failure by a supplier. Certain aspects of AbbVie's operations are highly dependent upon third party service providers. AbbVie relies on suppliers, vendors and other third party service providers to research, develop, manufacture, commercialize, promote and sell its products. **In addition, AbbVie relies on third party service providers for support of its information technology services**. Reliance on third party manufacturers reduces AbbVie's oversight and control of the manufacturing process. Some of these third party providers are subject to legal and regulatory requirements, privacy and security risks and market risks of their own. The failure of a critical third party service provider to meet its obligations could have a material adverse impact on AbbVie's operations and results. If any third party service providers have violated or are alleged to have violated any laws or regulations during the performance of their obligations to AbbVie, it is possible that AbbVie could suffer financial and reputational harm or other negative outcomes, including possible legal consequences. Significant safety or efficacy issues could arise for AbbVie's products, which could have a material adverse effect on AbbVie's revenues and financial condition. Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. Following regulatory approval, these products will be used over longer periods of time in many patients. Additional, and perhaps more extensive, studies may also be conducted, which may be sponsored by AbbVie but could also be sponsored by competitors, insurance companies, government institutions, scientists, investigators or other interested parties. If new safety or efficacy issues are reported or if new scientific information becomes available (including results of post-marketing Phase 4 trials), or if governments change standards regarding safety, efficacy or labeling, AbbVie may be required to amend the conditions of use for a product. For example, AbbVie may voluntarily provide or be required to provide updated information on a product's label or narrow its approved indication, either of which could reduce the product's market acceptance. If safety or efficacy issues with an AbbVie product arise, sales of the product could be halted by AbbVie or by regulatory authorities and regulatory action could be taken by such regulatory authorities. Safety or efficacy issues affecting suppliers' or competitors' products also may reduce the market acceptance of similar AbbVie products. New data about AbbVie's products, or products similar to its products, could negatively impact demand for AbbVie's products due to actual or perceived safety issues or uncertainty regarding efficacy and, in some cases, could result in product withdrawal. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of AbbVie's products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of AbbVie's products. AbbVie is subject to product liability claims and other lawsuits that may adversely affect its business, results of operations and reputation. In the ordinary course of business, AbbVie is the subject of product liability claims and lawsuits alleging that AbbVie's current or historical products or the products of other companies that it promotes have resulted or could result in an unsafe condition for or injury to patients. ~~For example, lawsuits are pending against Allergan, AbbVie's subsidiary, and certain of its former officers alleging they made misrepresentations and omissions regarding Allergan's textured breast implants.~~ Product liability claims and lawsuits and safety alerts or product recalls, regardless of their ultimate outcome, may have a material adverse effect on AbbVie's business, results of operations and reputation and on its ability to attract and retain customers. ~~2023 Form 10-K | 18~~ Consequences may also include additional costs, a decrease in market share for the product in question, lower revenue and exposure to other claims. **Additionally, some of these matters involve numerous plaintiffs and parties seeking large or indeterminate financial claims and may remain unresolved for several years**. AbbVie evaluates its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, AbbVie's product liability losses are self-insured. **2024 Form 10-K | 18** AbbVie is also the subject of other claims, legal proceedings and investigations in the ordinary course of business, which relate to intellectual property, commercial, securities and other matters. Adverse outcomes in such claims, legal proceedings and investigations may also adversely affect AbbVie's business, results of

operations and reputation. See Note 15, "Legal Proceedings and Contingencies" to the Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data." AbbVie cannot predict with certainty the outcome of these proceedings. AbbVie is subject to governmental regulations, and it can be costly to comply with these regulations and to develop compliant products and processes. AbbVie's products are subject to rigorous regulation by numerous international, supranational, federal and state authorities, as described in Item 1, "Business — Regulation — Discovery and Clinical Development," "Business — Regulation — Commercialization, Distribution and Manufacturing," and "Business — Regulation — Medical Devices." The process of obtaining regulatory approvals to market a pharmaceutical product can be costly and time consuming, and approvals may not be granted for future products, or additional indications or uses of existing products, on a timely basis, if at all. Delays in the receipt of, or failure to obtain approvals for, future products, or new indications and uses, could result in delayed realization of product revenues, reduction in revenues and substantial additional costs. The U. S. healthcare industry, in particular, is highly regulated and subject to frequent and substantial regulatory changes. It is expected that the U. S. healthcare industry will continue to be subject to increasing regulation as well as political and legal action, as future proposals to reform the healthcare system are considered by **federal the executive branch, Congress and state legislatures and local governments. Changes in healthcare policy may introduce additional and significant changes to healthcare regulation and the healthcare industry.** AbbVie cannot predict with certainty when additional changes in the healthcare industry in general, or the pharmaceutical industry in particular, will occur, or what the impact of such changes may be. In addition, AbbVie cannot guarantee that it will remain compliant with applicable regulatory requirements once approval has been obtained for a product. These requirements include, among other things, regulations regarding manufacturing practices, product labeling and advertising and post-marketing reporting, including adverse event reports and field alerts due to manufacturing quality concerns. AbbVie must incur expense and spend time and effort to ensure compliance with these complex regulations. Possible regulatory actions could result in substantial modifications to AbbVie's business practices and operations; refunds, recalls or seizures of AbbVie's products; a total or partial shutdown of production in one or more of AbbVie's or its suppliers' facilities while AbbVie or its supplier remedies the alleged violation; the inability to obtain future approvals; and withdrawals or suspensions of current products from the market. Any of these events could disrupt AbbVie's business and have a material adverse effect on its business and results of operations. Laws and regulations affecting government benefit programs could impose new obligations on AbbVie, require it to change its business practices, and restrict its operations. The health care industry is subject to federal, state and international laws and regulations pertaining to government benefit program reimbursements, rebates, price reporting and regulation and health care fraud and abuse. In the United States, these laws include anti-kickback and false claims laws, the Medicaid Rebate Statute, the Veterans Health Care Act, the U. S. Physician Payments Sunshine Act, the TRICARE program, the government pricing rules applicable to the Medicaid, Medicare Part B, 340B Drug Pricing Program and individual state laws relating to pricing and sales and marketing practices. Violations of such laws and regulations may be punishable by criminal and / or civil sanctions, including, in some instances, substantial fines, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid and Veterans Administration health programs. Such violations may also lead to product recalls and seizures, interruption of production leading to product shortages, import bans or denials of import certifications, delays or denials in the approvals of new products or supplemental approvals of current products pending resolution of the issues, and reputational harm, any of which would adversely affect AbbVie's business. These laws and regulations are broad in scope and are subject to change and evolving interpretations, which could require AbbVie to incur substantial costs associated with compliance or to alter one or more of its sales or marketing practices. In addition, violations of these laws and regulations, or allegations of such violations, could impose new obligations on AbbVie, require it to change its business practices and restrict its operations. 19 | **2023-2024** Form 10-K ~~Public health outbreaks, epidemics or pandemics, such as the coronavirus (COVID-19), have had, and could in the future have, an adverse impact on AbbVie's operations and financial condition. Public health outbreaks, epidemics or pandemics have had, and could in the future have, an adverse impact on AbbVie's operations and financial condition. The pandemic caused by the novel strain of coronavirus (COVID-19) caused many countries, including the United States, to declare national emergencies and implement preventive measures such as travel bans and shelter in place or total lock-down orders. The continuation or re-implementation of these bans and orders remains uncertain. The COVID-19 pandemic caused AbbVie to modify certain of its business practices, and AbbVie may take further actions as may be required by government authorities or as AbbVie determines are in the best interests of AbbVie's employees, patients, customers and business partners.~~ The international nature of AbbVie's business subjects it to additional business risks that may cause its revenue and profitability to decline. AbbVie's business is subject to risks associated with doing business internationally, including in emerging markets. Net revenues outside of the United States made up approximately **23-24%** of AbbVie's total net revenues in **2023-2024**. The risks associated with AbbVie's operations outside the United States include: • fluctuations in currency exchange rates; • changes in medical reimbursement policies and programs and pricing restrictions; • multiple legal and regulatory requirements that are subject to change and that could restrict AbbVie's ability to manufacture, market and sell its products; • differing local product preferences and product requirements; • trade protection measures and import or export licensing requirements; • international trade disruptions or disputes; • difficulty in establishing, staffing and managing operations; • differing labor regulations; • potentially negative consequences from changes in or interpretations of tax laws; • political and economic instability; • **conflicts or crises in individual countries or regions, including terrorist activities or wars;** • sovereign debt issues; • price and currency exchange controls, limitations on participation in local enterprises, expropriation, nationalization and other governmental action and regulation; • inflation, recession and fluctuations in interest rates; • restrictions on transfers of funds; • potential deterioration in the economic position and credit quality of certain non-U. S. countries; and • potential penalties or other adverse consequences for violations of anti-corruption, anti-bribery and other similar laws and regulations, including the United States Foreign Corrupt Practices Act and the United Kingdom Bribery Act. If AbbVie does not effectively and profitably commercialize its

products, AbbVie's revenues and financial condition could be adversely affected. AbbVie must effectively and profitably commercialize its principal products by creating and meeting continued market demand; achieving market acceptance and generating product sales; ensuring that the active pharmaceutical ingredient (s) for a product and the finished product are manufactured in sufficient quantities and in compliance with requirements of the FDA and similar foreign regulatory agencies and with acceptable quality and pricing to meet commercial demand; and ensuring that the entire supply chain efficiently and consistently delivers AbbVie's products to its customers. The commercialization of AbbVie products may not be successful due to, among other things, unexpected challenges from competitors, new safety issues or concerns being reported that may impact or narrow approved indications, the relative price of AbbVie's product as compared to alternative treatment options and changes to a product's label that further restrict its marketing. If the commercialization of AbbVie's principal products is unsuccessful, AbbVie's revenues and financial condition could be adversely affected. ~~2023 Form 10-K | 20~~ AbbVie may acquire other businesses, license rights to technologies or products, form alliances, or dispose of assets, which could cause it to incur significant expenses and could negatively affect profitability. AbbVie from time to time pursues acquisitions, technology licensing arrangements, joint ventures and strategic alliances, and / or disposes of some of its assets, as part of its business strategy. AbbVie may not complete these transactions in a timely manner, on a cost-effective basis, or at all, and may not realize the expected benefits. If AbbVie is successful in making an acquisition, the products and technologies that are acquired may not be successful or may require significantly greater resources and investments than originally anticipated. AbbVie may not be able to integrate acquisitions successfully into its existing business and could incur or assume significant debt and unknown or contingent liabilities. AbbVie could also **2024 Form 10-K | 20** experience negative effects on its reported results of operations from acquisition or disposition-related charges, amortization of expenses related to intangibles and charges for impairment of long-term assets. These effects could cause a deterioration of AbbVie's credit rating and result in increased borrowing costs and interest expense. Additionally, changes in AbbVie's structure, operations, revenues, costs, or efficiency resulting from major transactions such as acquisitions, divestitures, mergers, alliances, joint ventures, restructurings or other strategic initiatives, may result in greater than expected costs, may take longer than expected to complete or encounter other difficulties, including the need for regulatory approval where appropriate. AbbVie is dependent on wholesale distributors for distribution of its products in the United States and, accordingly, its business and results of operations could be adversely affected if they encounter financial or other difficulties. In ~~2023-2024~~, three wholesale distributors (McKesson Corporation, Cardinal Health, Inc. and ~~AmerisourceBergen Corporation~~ **Cencora, Inc.**) accounted for substantially all of AbbVie's pharmaceutical product sales in the United States. If one of its significant wholesale distributors encounters financial or other difficulties, such distributor may decrease the amount of business that it does with AbbVie, and AbbVie may be unable to collect all the amounts that the distributor owes it on a timely basis or at all, which could adversely affect AbbVie's business and results of operations. AbbVie has debt obligations that could adversely affect its business and its ability to meet its obligations. The amount of debt that AbbVie has incurred and intends to incur could have important consequences to AbbVie and its investors. These consequences include, among other things, requiring a portion of AbbVie's cash flow from operations to make interest payments on this debt and reducing the cash flow available to fund capital expenditures and other corporate purposes and to grow AbbVie's business. To the extent AbbVie incurs additional indebtedness or interest rates increase, these risks could increase further. In addition, AbbVie's cash flow from operations may not be sufficient to repay all of the outstanding debt as it becomes due, and AbbVie may not be able to borrow money, sell assets, or otherwise raise funds on acceptable terms, or at all, to refinance its debt. AbbVie may need additional financing in the future to meet its capital needs or to make opportunistic acquisitions, and such financing may not be available on favorable terms, if at all. AbbVie may need additional financing in the future to meet its capital needs or to make opportunistic acquisitions. For example, it may need to increase its investment in research and development activities. The capital and credit markets may experience extreme volatility and disruption, which may lead to uncertainty and liquidity issues for both borrowers and investors, and AbbVie may be unable to obtain any desired additional financing on terms favorable to it, if at all. If AbbVie loses its investment grade credit rating or adequate funds are not available on acceptable terms, AbbVie may be unable to fund its expansion, successfully develop or enhance products, or respond to competitive pressures, any of which could negatively affect AbbVie's business. If AbbVie raises additional funds by issuing debt or entering into credit facilities, it may be subject to limitations on its operations due to restrictive covenants. Failure to comply with these covenants could adversely affect AbbVie's business. AbbVie depends on information technology and a failure of, or significant disruption to, those systems **, or a failure to adequately adopt emerging technologies such as artificial intelligence,** could have a material adverse effect on AbbVie's business. AbbVie relies on sophisticated software applications and complex information technology systems (including cloud services) to operate its business, which are inherently vulnerable to malicious intrusion, random attack, loss of data privacy, disruption, degradation or breakdown. Certain of these applications and systems are managed, hosted, provided or used by third parties. Data privacy or security breaches of our internal systems or those of our information technology vendors may in the future result in the failure of critical business operations. Such breaches may cause sensitive data, including intellectual property, trade secrets or personal information belonging to AbbVie, its patients, customers **, employees** or business partners, to be exposed to unauthorized persons or to the public. To date, neither AbbVie's business nor operations have been materially impacted by such incidents, however, the healthcare industry remains a target of cyber-attacks. Cybersecurity attacks and incidents are increasing in their frequency, sophistication and intensity and, due to the nature of some of these attacks, there ~~21 | 2023 Form 10-K~~ is a risk that they may remain undetected for a period of time. AbbVie's investments in the protection of its data and information technology and its efforts to monitor its systems on an ongoing basis may be insufficient to prevent compromises in AbbVie's information technology systems that could have a material adverse effect on AbbVie's business. Such adverse consequences could include loss of revenue or the loss of critical or sensitive information from AbbVie's or third-party providers' databases or information technology systems and could also result in legal, financial, reputational or business harm to AbbVie and potentially substantial

remediation costs. In addition, AbbVie's cyber insurance may not be sufficient to **21 | 2024 Form 10- K** cover the financial, legal, business or reputational losses that may result from an interruption or breach of AbbVie systems or those of our third-party vendors. **Additionally, AbbVie utilizes artificial intelligence (AI) and other emerging technologies in select applications to support its operations. These technologies may present opportunities for AbbVie's business but may also entail risks, including that AI- generated analyses utilized by AbbVie could be deficient or exacerbate regulatory, cybersecurity or other significant risks. Further, our failure to effectively implement these technologies could hinder our ability to compete, as competitors' advancements in AI may lead to more efficient operations.** AbbVie's balances of intangible assets, including developed product rights and goodwill acquired, are subject to impairment testing and may result in impairment charges, which may adversely affect AbbVie's results of operations and financial condition. A significant amount of AbbVie's total assets is related to acquired intangibles and goodwill. As of December 31, **2023-2024**, the carrying value of AbbVie's developed product rights and other intangible assets was \$ **55-60**. **6-1** billion and the carrying value of AbbVie's goodwill was \$ **32-35**. **3-0** billion. AbbVie's developed product rights are stated at cost, less accumulated amortization. AbbVie determines original fair value and amortization periods for developed product rights based on its assessment of various factors impacting estimated useful lives and cash flows of the acquired products. Significant adverse changes to any of these factors require AbbVie to perform an impairment test on the affected asset and, if evidence of impairment exists, require AbbVie to take an impairment charge with respect to the asset. For assets that are not impaired, AbbVie may adjust the remaining useful lives. Such a charge could adversely affect AbbVie's results of operations and financial condition. AbbVie's other significant intangible assets include in- process research and development (IPR & D) intangible projects, acquired in recent business combinations, which are indefinite- lived intangible assets. For IPR & D assets, the risk of failure is significant, and there can be no certainty that these assets ultimately will yield successful products. AbbVie's ability to realize value on these significant investments is often contingent upon, among other things, regulatory approvals and market conditions. As such, IPR & D assets may become impaired and / or be written off at some point in the future if the associated research and development effort is abandoned or is curtailed. Goodwill and AbbVie's IPR & D intangible assets are tested for impairment annually, or when events occur, or circumstances change that could potentially reduce the fair value of the reporting unit or intangible asset. Impairment testing compares the fair value of the reporting unit or intangible asset to its carrying amount. A goodwill or IPR & D impairment, if any, would be recorded in operating income and could have a material adverse effect on AbbVie's results of operations and financial condition. Failure to attract, develop and retain highly qualified personnel could affect AbbVie's ability to successfully develop and commercialize products. AbbVie's success is largely dependent on its continued ability to attract, develop and retain diverse, highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical research and development, governmental regulation and commercialization. Competition for qualified personnel in the biopharmaceutical field is intense and increasing. AbbVie cannot be sure that it will be able to attract and retain quality personnel or that the costs of doing so will not materially increase. The illegal distribution and sale by third parties of counterfeit or unregistered versions of AbbVie products could have a material adverse impact on its reputation, business and results of operations. Third parties may illegally obtain, distribute, and sell counterfeit or illegally diverted from their intended market versions of AbbVie products. These versions of product would not meet AbbVie's rigorous manufacturing, testing, distribution and quality standards. A patient who receives a counterfeit, stolen, or diverted drug may be at risk for a number of dangerous health consequences. The prevalence of counterfeit / diverted medicines is an industry- wide issue due to a variety of factors, including the adoption of e- commerce, **which increased during the COVID-19 pandemic**, greatly enhancing consumers' ability to obtain prescriptions and other medical treatments via the internet in lieu of traditional brick and mortar pharmacies. This can expose patients to greater risks as the internet is a preferred vehicle for dangerous counterfeit / diverted product offers and scams because of the anonymity it **2024 Form 10- K | 22** affords. AbbVie's reputation and business could suffer harm as a result of counterfeit **2023 Form 10- K | 22** or diverted drugs sold under its brand name which may also result in reduced revenues that could negatively affect our results of operation. Other factors can have a material adverse effect on AbbVie's profitability and financial condition. Many other factors can affect AbbVie's results of operations, cash flows and financial condition, including: • changes in or interpretations of laws and regulations, including changes in accounting standards, taxation requirements, product marketing application standards, data privacy laws, particularly in the European Union and the United States and environmental laws; • differences between the fair value measurement of assets and liabilities and their actual value, particularly for pension and post- employment benefits, stock- based compensation, intangibles and goodwill; and for contingent liabilities such as litigation and contingent consideration, the absence of a recorded amount, or an amount recorded at the minimum, compared to the actual amount; • changes in the rate of inflation (including the cost of raw materials, commodities and supplies), interest rates, market value of AbbVie's equity investments and the performance of investments held by it or its employee benefit trusts; • changes in the creditworthiness of counterparties that transact business with or provide services to AbbVie or its employee benefit trusts; • environmental liabilities in connection with AbbVie's manufacturing processes and distribution logistics, including the handling of hazardous materials; • changes in the ability of third parties that provide information technology, accounting, human resources, payroll and other outsourced services to AbbVie to meet their contractual obligations to AbbVie; • the failure, or perceived failure, **or pursuit** of achieving environmental, social and governance objectives; • information loss or damage to AbbVie's reputation, brand, image or goodwill due to increased use of social media platforms; • business interruptions stemming from natural disasters, such as climate change, earthquakes, hurricanes, flooding, fires, or efforts taken by third parties to prevent or mitigate such disasters; and • changes in business, economic and political conditions, including: war, political instability, terrorist attacks, the threat of future terrorist activity and related military action; natural disasters; **pandemics and epidemics**, the cost and availability of insurance due to any of the foregoing events; labor disputes, strikes, slow- downs, or other forms of labor or union activity; and pressure from third- party interest groups. Risks Related to AbbVie's Common Stock AbbVie cannot guarantee the timing, amount, or payment of

dividends on its common stock or the repurchase of its common stock. Although AbbVie expects to pay regular cash dividends, the timing, declaration, amount and payment of future dividends to stockholders will fall within the discretion of AbbVie's board of directors. The board's decisions regarding the payment of dividends will depend on many factors, such as AbbVie's financial condition, earnings, capital requirements, debt service obligations, industry practice, legal requirements, regulatory constraints and other factors that the board deems relevant. For more information, see Item 5, "Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities." AbbVie's ability to pay dividends and repurchase shares under its ~~share~~ **stock** repurchase program will depend on its ongoing ability to generate cash from operations and access capital markets. AbbVie cannot guarantee that it will continue to pay a dividend in the future. An AbbVie stockholder's percentage of ownership in AbbVie may be diluted in the future. In the future, a stockholder's percentage ownership in AbbVie may be diluted because of equity issuances for capital market transactions, equity awards that AbbVie will be granting to AbbVie's directors, officers and employees, acquisitions or other purposes. AbbVie anticipates its compensation committee will grant additional stock options or other stock-based awards to its employees. Such awards will have a dilutive effect on AbbVie's earnings per share, which could adversely affect the market price of AbbVie's common stock. From time to time, AbbVie will issue additional options or other stock-based awards to its employees under AbbVie's employee benefits plans. 23 | ~~2023~~ **2024** Form 10-K In addition, AbbVie's amended and restated certificate of incorporation authorizes AbbVie to issue, without the approval of AbbVie's stockholders, one or more classes or series of preferred stock having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over AbbVie's common stock respecting dividends and distributions, as AbbVie's board of directors generally may determine. The terms of one or more classes or series of preferred stock could dilute the voting power or reduce the value of AbbVie's common stock. For example, AbbVie could grant the holders of preferred stock the right to elect some number of AbbVie's directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences AbbVie could assign to holders of preferred stock could affect the residual value of the common stock. Certain provisions in AbbVie's amended and restated certificate of incorporation and amended and restated by-laws, and of Delaware law, may prevent or delay an acquisition of AbbVie, which could decrease the trading price of AbbVie's common stock. AbbVie's amended and restated certificate of incorporation and amended and restated by-laws contain, and Delaware law contains, provisions that are intended to deter coercive takeover practices and inadequate takeover bids by encouraging prospective acquirors to negotiate with AbbVie's board of directors rather than to attempt a hostile takeover. These provisions include, among others: • the inability of AbbVie's stockholders to call a special meeting; • the division of AbbVie's board of directors into three classes of directors, with each class serving a staggered three-year term; • a provision that stockholders may only remove directors for cause; • the ability of AbbVie's directors, and not stockholders, to fill vacancies on AbbVie's board of directors; and • the requirement that the affirmative vote of stockholders holding at least 80% of AbbVie's voting stock is required to amend certain provisions in AbbVie's amended and restated certificate of incorporation and AbbVie's amended and restated by-laws relating to the number, term and election of AbbVie's directors, the filling of board vacancies, the calling of special meetings of stockholders and director and officer indemnification provisions. In addition, Section 203 of the Delaware General Corporation Law provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15% of the outstanding voting stock of a Delaware corporation shall not engage in any business combination with that corporation, including by merger, consolidation or acquisitions of additional shares, for a three-year period following the date on which that person or its affiliates becomes the holder of more than 15% of the corporation's outstanding voting stock. AbbVie believes these provisions protect its stockholders from coercive or otherwise unfair takeover tactics by requiring potential acquirors to negotiate with AbbVie's board of directors and by providing AbbVie's board of directors with more time to assess any acquisition proposal. These provisions are not intended to make the company immune from takeovers. However, these provisions apply even if the offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that AbbVie's board of directors determines is not in the best interests of AbbVie and AbbVie's stockholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors. ~~2023~~ **2024** Form 10-K | 24 CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS This Annual Report on Form 10-K contains certain forward-looking statements regarding business strategies, market potential, future financial performance and other matters. The words "believe," "expect," "anticipate," "project" and similar expressions and uses of future or conditional verbs, generally identify "forward looking statements," which speak only as of the date the statements were made. The matters discussed in these forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those expressed or implied in the forward-looking statements. In particular, information included under Item 1, "Business," Item 1A, "Risk Factors," and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" contain forward looking statements. Where, in any forward looking statement, an expectation or belief as to future results or events is expressed or implied, such expectation or belief is based on the current plans and expectations of AbbVie management and expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the expectation or belief will result or be achieved or accomplished. Factors that could cause actual results or events to differ materially from those anticipated include, but are not limited to, the matters described under Item 1A, "Risk Factors" and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations." AbbVie does not undertake, and specifically declines, any obligation to update the forward-looking statements included in this Annual Report on Form 10-K to reflect events or circumstances after the date hereof, unless AbbVie is required by applicable securities law to do so.