

## Risk Factors Comparison 2024-02-22 to 2023-02-23 Form: 10-K

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This section describes the material risks to our business, which should be considered carefully in addition to the other information in this report and our other filings with the SEC. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. Additionally, our business is subject to general risks applicable to any company, such as economic conditions, geopolitical events, extreme weather and natural disasters. If known or unknown risks or uncertainties materialize, our business operations, financial condition, operating results (including components of our financial results), cash flows, prospects, reputation or credit ratings could be adversely affected now and in the future, potentially in a material way. The following discussion of risk factors contains forward- looking statements, as discussed in the Forward- Looking Information and Factors that May Affect Future Results section ~~in this Form 10-K~~. **RISKS RELATED TO OUR BUSINESS, INDUSTRY AND OPERATIONS: MANAGED CARE TRENDS** Private ~~payers~~ **payors**, such as health plans, and other managed care entities, such as PBMs, continue to take action to manage the utilization and costs of drugs **in the U. S., the single largest market for biopharmaceutical products**. The negotiating power of MCOs and other private third- party ~~payers~~ **payors** has increased due to consolidation, and they, along with **state and federal** governments, increasingly employ formularies to control costs and encourage utilization of certain drugs, including through the use of ~~formulary inclusion~~ **deductibles, utilization management tools, cost sharing** or favorable formulary placement. **They may demand rebates from biopharmaceutical manufacturers for preferred placement on a drug formulary. The growing availability and use of innovative specialty pharmaceutical medicines that treat rare or life threatening conditions, typically with a relatively higher cost as compared to other types of pharmaceutical products, also has generated increased payor interest in development of cost- containment strategies**. These initiatives have increased consumers' interest **in drug prices** and input in medication choices, as they pay for a larger portion of their prescription costs and may cause them to favor lower- cost generic alternatives. We may fail to obtain or maintain timely or adequate pricing or formulary placement of our products, or fail to obtain such formulary placement at favorable pricing ~~net~~. ~~The growing availability and use of rebates innovative specialty pharmaceutical medicines that treat rare or life- threatening conditions, which typically have smaller patient populations, combined with their relative higher cost as compared to other types of pharmaceutical products, also has generated increased payer interest in developing cost- containment strategies targeted to this sector.~~ Third- party ~~payers~~ **payors** also use additional measures such as new- to- market blocks, exclusion lists, indication- based pricing and value- based pricing / contracting to improve their cost containment efforts **and cost efficiency**. Such ~~payers~~ **payors** are also increasingly imposing utilization management tools, ~~such as clinical protocols,~~ requiring prior authorization for a branded product ~~if a generic product is available~~ or requiring the patient to first fail on one or more ~~generic~~ **other** products before permitting access to a **particular** branded medicine. As the U. S. private third- party ~~payer~~ **payor** market consolidates further, and as ~~more drugs~~ **the IRA prices** become **publicly** available ~~in generic form~~, we may face greater pricing pressure from private third- party ~~payers~~ **payors** as they continue to drive more of their patients to use lower cost ~~generic~~ alternatives. **Pfizer Inc. 2023 Form 10- K16 or seek even larger rebates to control costs or offset losses from the IRA. For additional information on the IRA, see the Item 1. Business — Government Regulation and Price Constraints section**. Also, business arrangements in this area are subject to a high degree of government scrutiny, and available safe harbors under applicable federal and state fraud and abuse laws are subject to change through legislative and regulatory action, as well as evolving judicial interpretations. Our approach to these arrangements may also be informed by such government and industry guidance. **COMPETITIVE PRODUCTS** Competitive product launches **have and** may erode future sales of our products, including our existing products and those currently under development, or result in ~~unanticipated~~ product obsolescence. Such launches continue to occur, and potentially competitive products are in various stages of development. We cannot predict with accuracy the timing or impact of the introduction of competitive products that treat or prevent diseases and conditions like those treated or prevented by our in- line products and product candidates. Some of our competitors may have competitive, technical or other advantages over us for the development of technologies and processes or greater experience in particular therapeutic areas, and 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. Our products have been competing and may continue to compete, and our product candidates may compete, against products or product candidates that offer higher rebates or discounts, **exclusionary contracting**, lower prices, equivalent or superior efficacy, better safety profiles, easier administration, earlier market availability or other competitive features. If we are unable to compete effectively, this could reduce sales, which could negatively impact our results of operations. In addition, competition from manufacturers of generic drugs, including from generic versions of competitors' branded products that lose their market exclusivity, is a major challenge for our branded products. Certain of our products have experienced significant generic competition over the last few years. ~~For additional information, see~~ **We anticipate a more significant impact of reduced revenues from patent expiries in 2026 through 2030 as several of our in- line products experience patent- based expirations. See** the Item 1. Business — Patents and Other Intellectual Property Rights section ~~in this Form 10-K~~. In China, we expect to continue to face intense competition by certain generic manufacturers, which ~~have~~ **has** resulted, and may result in the future, in price cuts and volume loss of some of our products. In addition, our patented products may face generic or biosimilar competition before patent exclusivity expires, including from “ at- risk ” launch (despite pending patent infringement litigation against the generic or biosimilar product) by a

manufacturer of a generic or biosimilar version of one of our patented products. Generic and biosimilar manufacturers have filed or could file applications with the FDA seeking approval of product candidates that they claim do not infringe our **or our collaboration and licensing partners'** patents or claim that our **or our collaboration and licensing partners'** patents are not valid. **Our We and our** licensing and collaboration partners also face challenges **in various jurisdictions** by generic drug manufacturers to patents covering products for which we have **patent rights**, licenses or co-promotion rights. **See Note 16A1**. We may become subject to competition from biosimilars referencing our biologic products if competitors are able to obtain marketing approval for such biosimilars. We also commercialize biosimilar products that compete with products of others, including other biosimilar products. The entry to the market of competing biosimilars is expected to increase pricing pressures on our biosimilar products. Uptake of our biosimilars may be lower due to various factors, such as anti-competitive practices, access challenges where our product may not receive appropriate coverage / reimbursement access or remains in a disadvantaged position relative to an innovator product, physician reluctance to prescribe biosimilars for existing patients taking the **innovative-reference** product, or misaligned financial incentives for certain prescribers. For additional information on competition our products face, see the Item 1. Business — Competition section **in this Form 10-K**. **Pfizer Inc. 2022 Form 10-K14** CONCENTRATION We recorded direct product and / or Alliance revenues of more than \$ 1 billion for each of **ten-nine** products that collectively accounted for **82-64 %** of our total **Total** revenues in **2022-2023**. In particular, Comirnaty and Paxlovid together accounted for **57-19 %** of our total **Total** revenues in **2022-2023**. **See For additional information, see** Notes 1 and 17. If these products or any of our other major products were to **, or continue to (if applicable),** experience loss of patent protection (if applicable), changes in prescription or vaccination purchasing or growth rates, reduced product demand, material product liability litigation, unexpected side effects or safety concerns, regulatory proceedings or investigations, lower governmental and / or regulatory confidence, negative publicity affecting doctor or patient confidence, pressure from competitive products, changes in labeling, pricing and access pressures or supply shortages or if a new, more effective product should be introduced, the adverse impact on our revenues could be significant **and our revenue forecasts and expectations could prove to be inaccurate and we may fail to meet these expectations**. In particular, certain of our products have experienced patent-based expirations or loss of regulatory exclusivity in certain markets in the last few years **. We anticipate a more significant impact of reduced revenues from patent expiries in 2026 through 2030 as several of our in-line products experience patent-based expirations. In addition**, and patents covering a number of our best-selling products are, or have been, the subject of pending legal challenges. For additional information on our patents, see the Item 1. Business — Patents and Other Intellectual Property Rights section **in this Form 10-K**. For Comirnaty and Paxlovid, while we believe that these products have the potential to provide ongoing revenue streams for Pfizer for the foreseeable future, revenues of these products following the COVID-19 pandemic **have decreased substantially** may not be at similar levels as those generated during the pandemic. **For 2023, and our revenue guidance current expectations for total COVID-19 product revenues in Comirnaty and Paxlovid as of January 31, 2023-2024 are** is significantly lower than the **total 2022-2023** revenues from these **COVID-19** products. For information on risks associated with Comirnaty and Paxlovid, see the COVID-19 section below. In addition, **certain** we sell our prescription biopharmaceutical products, with the exception of Paxlovid, principally to wholesalers, but we also sell directly to retailers, hospitals, clinics, government agencies and pharmacies. In 2022, we principally sold Paxlovid to government agencies. We primarily sell our **customers account for a significant portion of** vaccines in the U. S. directly to the federal government, CDC, wholesalers, individual provider offices, retail pharmacies and integrated delivery systems. Outside the U. S., we primarily sell our **revenues** vaccines to government and non-government institutions. For additional information, see Note 17C. If one of our significant customers should encounter financial or other difficulties, it might decrease the amount of business such customer does with us and / or we might be unable to timely collect all the amounts that such customer owes us or at all, which could negatively impact our results of operations. In addition, we expect that consolidation and integration of pharmacy chains and wholesalers will increase competitive and pricing pressures on pharmaceutical manufacturers, including us. **See Note 17C for a discussion of our significant customers**. RESEARCH AND DEVELOPMENT The discovery and development of new products, as well as the development of additional uses for existing products, are necessary for the continued strength of our business. Our product lines must be replenished over time to offset revenue losses when products lose exclusivity or market share or to respond to healthcare and innovation trends, as well as to provide for earnings growth, primarily through internal R & D or through collaborations, acquisitions, JVs, licensing or other arrangements. Growth depends in large part on our ability to identify and develop **Pfizer Inc. 2023 Form 10-K17** new products or new indications for existing products that address unmet medical needs and receive reimbursement from **payers-payors**. However, balancing current growth, investment for future growth and the delivery of shareholder return remains a major challenge. The costs of product development continue to be high **and are growing**, as are regulatory requirements in many therapeutic areas, which may affect **the complexity of drug trials, and** the number of candidates we are able to fund as well as the sustainability of the R & D portfolio. Decisions made early in the development process of a drug or vaccine candidate can have a substantial impact on the marketing strategy and **payer-payor** reimbursement possibilities if the candidate receives regulatory approval. We try to plan clinical trials prudently and to reasonably anticipate and address challenges, but there is no assurance that an optimal balance between trial conduct, speed and desired outcome will be achieved. Additionally, our product candidates can fail at any stage of the R & D process, and may not receive regulatory approval even after many years of R & D. We may fail to correctly identify **compounds or** indications for which our science is promising or allocate R & D investment resources efficiently, and failure to invest in the right technology platforms, therapeutic areas, product classes, geographic markets and / or licensing opportunities could adversely impact the productivity of our pipeline. Further, even if we identify areas with the greatest commercial potential, the scientific approach may not succeed despite the significant investment required for R & D, and the product may not be as competitive as expected because of the highly dynamic **regulatory and market environment environments** and the hurdles in terms of access **, coverage** and reimbursement. For example, **certain of** our gene therapy product candidates are based

on a novel technology with only a few handful of gene therapies approved to date, which makes make it difficult to predict the time and cost of development and the ability to obtain regulatory approval. Further, gene therapy may face difficulties in gaining the acceptance of patients or the medical community. GLOBAL OPERATIONS We operate on a global scale and could be affected by currency and interest rate fluctuations; capital and exchange controls; local and global economic conditions including inflation, recession, volatility and / or lack of liquidity in capital markets; expropriation and other restrictive government actions; changes in intellectual property; legal protections and remedies; trade regulations; tax laws and regulations; and procedures and actions affecting approval, production, pricing, and marketing of, reimbursement for and access to our products, as well as impacts of political or civil unrest or military action, including the ongoing conflict conflicts between Russia and Ukraine and its in the Middle East and their economic consequences, geopolitical instability, terrorist activity, unstable governments and legal systems, inter- governmental disputes, public health outbreaks, epidemics, pandemics, natural disasters or disruptions related to climate change. Some emerging market countries may be particularly vulnerable to periods of financial , economic or political instability or significant currency fluctuations or may have limited resources for healthcare spending. As a result of these and other factors, our strategy to grow in emerging markets may not be successful, and any growth rates in these markets may not be sustainable. Additionally, local economic conditions may adversely affect the ability of payers payors, as well as our distributors, customers, suppliers and service providers, to pay for our products, or otherwise to buy necessary inventory or raw materials, and to perform their obligations under agreements with us. Government financing and economic pressures can lead to negative pricing pressure in various markets where governments take an active role in setting prices, access criteria (e. g., through health technology assessments) or other means of cost control. For additional information on government pricing pressures, see the Item 1. Business — Government Regulation and Price Constraints section in this Form 10-K. We continue to monitor the global trade environment and potential trade conflicts and impediments that could impact our business. If trade restrictions or tariffs reduce global economic activity, potential impacts could include declining sales; increased costs; volatility in foreign exchange rates; a decline in the value of our financial assets and pension plan investments; required increases of our pension funding obligations; increased government cost control efforts; delays or failures in the performance of customers, suppliers and other third parties on whom we may depend for the performance of our business; and the risk that our allowance for doubtful accounts may not be adequate. Pfizer Inc. 2022 Form 10-K 15 We operate in many countries and transact in many different currencies. Changes in the value of those currencies relative to the U. S. dollar, or high inflation or deflation in those countries, can impact our revenues, costs and expenses and our financial guidance. Significant portions of our revenues, costs and expenses, as well as our substantial international net assets, are exposed to exchange rate changes. 58-54 % of our total 2022-2023 revenues were derived from international operations, including 26-24 % from Europe and 20 % from Japan, China and the rest of the Asia Pacific region. Future changes in exchange rates or economic conditions and the impact they may have on our results of operations, financial condition or business are difficult to predict. For additional information about our exposure to foreign currency risk, see the Analysis of Financial Condition, Liquidity, Capital Resources and Market Risk section within MD & A. In addition, our borrowing, pension benefit and postretirement benefit obligations and interest- bearing investments are subject to risk from changes in interest and exchange rates. The risks related to interest- bearing investments and borrowings and the measures we have taken to help contain them are discussed in the Analysis of Financial Condition, Liquidity, Capital Resources and Market Risk section within MD & A and Note 7E. For additional details on critical accounting estimates and assumptions for our benefit plans, see the Significant Accounting Policies and Application of Critical Accounting Estimates and Assumptions — Benefit Plans section within MD & A and Note 11. PRODUCT MANUFACTURING, SALES AND MARKETING RISKS We could encounter difficulties, delays or inefficiencies in our supply chain, product manufacturing and distribution networks, as well as sales or marketing, due to regulatory actions, shut-downs, work stoppages or strikes, approval delays, withdrawals, recalls, penalties, supply disruptions, shortages or stock- outs at our facilities or third- party facilities that we rely on, reputational harm, the impact to our facilities due to health pandemics or natural or man- made disasters, including as a result of climate change, product liability or unanticipated costs. Examples of such difficulties or delays include the inability to increase or maintain production capacity commensurate with demand; challenges related to component materials to maintain supply and / or appropriate quality standards throughout our supply network and / or comply with applicable regulations; inability to supply certain products due to voluntary product recalls; and supply chain disruptions at our facilities or at a supplier or vendor. In addition, we engage contract manufacturers, and, from time to time, our contract manufacturers may face difficulties or are unable to manufacture our products at the necessary quantity or quality levels. Regulatory agencies periodically inspect our manufacturing facilities, as well as third- party facilities that we rely on, to evaluate compliance with cGMP or other applicable requirements. Failure to comply with these requirements may subject us to possible legal or regulatory actions, such as warning letters, suspension of manufacturing, seizure of product, injunctions, debarment, product recalls, delays or denials of product approvals, import bans or denials of import certifications. In 2021, Pfizer recalled all lots of Chantix in the U. S. due to the presence of a nitrosamine, N- nitroso- varenicline, at or above the FDA interim acceptable intake limit. We currently also Regulatory authorities outside the U. S. have issued updated guidance on nitrosamine acceptable intake levels. With this recently issued guidance, which included an updated intake level for N- nitroso- varenicline, we expect to make regulatory submissions in 2024 to potentially enable Chantix to return to market outside the U. S., and our related discussions with FDA are ongoing. Pfizer Inc. 2023 Form 10- K 18 Our manufacturing facility in Rocky Mount, NC was damaged by a tornado voluntary recall across multiple markets and a global pause in July 2023 shipments of Chantix. While Technical solutions are being pursued to reduce nitrosamine levels in Chantix to enable return to market. In response to requests from various regulatory authorities, manufacturers manufacturing across the pharmaceutical industry, including Pfizer, are evaluating their product portfolios for the potential presence or formation of nitrosamines. This has resumed, led to additional voluntary recalls initiated for other -- the supply of medicines impacted by products in 2022, and may lead to additional recalls or other -- the market actions for Pfizer products tornado is expected to be

**affected through 2024. See the Overview of Our Performance, Operating Environment, Strategy and Outlook — Our Operating Environment section within MD & A.** COLLABORATIONS AND OTHER RELATIONSHIPS WITH THIRD PARTIES We depend on third- party collaborators, service providers, and others in the research, development, manufacturing and commercialization of our products and product candidates and also enter into JVs and other business development transactions. To achieve expected longer- term benefits, we may make substantial upfront payments as part of these transactions, which may negatively impact our earnings or cash flows. We rely heavily on these parties for multiple aspects of our drug development, manufacturing and commercialization activities, but we do not control many aspects of those activities. We also outsource certain services, including activities related to transaction processing, accounting, IT, manufacturing, clinical trial recruitment and execution, clinical lab services, non- clinical research, safety services, integrated facilities management and other areas. Failure by one or more of the third- party collaborators, service providers and others to complete activities on schedule or in accordance with our expectations or to meet their contractual or other obligations to us; failure of one or more of these parties to comply with applicable laws or regulations; disruptions in one or more of these parties’ businesses, including unexpected demand for or shortage of raw materials or components, cyber- attacks on supplier systems, labor disputes or shortage and inclement weather, as well as natural or man- made disasters or pandemics; or any disruption in the relationships between us and these parties ~~may~~ **have or** could delay or prevent the development, approval, manufacturing or commercialization of our products and product candidates, expose us to suboptimal quality of service delivery or deliverables, result in repercussions such as missed deadlines or other timeliness issues, erroneous data and supply disruptions, and could also result in non- compliance with legal or regulatory requirements or industry standards or subject us to reputational harm, all with potential negative implications for our product pipeline and business. Further, our Alliance revenues will be adversely affected by the termination or expiration of collaboration and co- promotion agreements that we have entered into and that we may enter into from time to time. COUNTERFEIT PRODUCTS Our reputation, in- line and pipeline portfolios render our medicines and vaccines prime targets for counterfeiters. Counterfeits pose a significant risk to patient health and safety because of the conditions under which they are manufactured — often in unregulated, unlicensed, uninspected, and unsanitary sites — as well as the lack of regulation of their contents. Failure to mitigate this threat could adversely impact Pfizer’ s patients, potentially causing them harm. This situation, in turn, may result in the loss of patient confidence in the Pfizer name and in the integrity of our medicines and vaccines, and potentially impact our business through lost sales, product recalls, and possible litigation. The prevalence of counterfeit medicines is an industry- wide issue due to a variety of factors, including the adoption of e- commerce. The increased adoption during the COVID- 19 pandemic further exposed consumers to fake prescription treatments via the internet as access to traditional brick and mortar pharmacies or authorized full- service internet pharmacies that offer authentic treatments may have been hindered. The internet exposes patients to greater risk as it is a preferred vehicle for dangerous counterfeit offers and scams that target unsuspecting consumers. Traffic to these generally deceptive pharmacy sites is largely driven by misplaced trust in sophisticated internet retailers and social media offers coupled with the convenience e- commerce affords consumers. Counterfeiters generally target any medicine or vaccine boasting strong demand and we have observed heightened counterfeit and fraud attempts to our internal medicine portfolio, as well as products utilized in the treatment of COVID- 19. We consistently invest in an enterprise- wide strategy to aggressively combat counterfeit threats by educating patients and ~~health- healthcare care~~ **health- healthcare care** providers about the risks, investing in innovative technologies to detect and disrupt sophisticated internet offers and scams, proactively monitoring and ~~Pfizer Inc. 2022 Form 10- K16~~ interdicting supply with the help of law enforcement, and advising legislators and regulators. However, our efforts and those of others may not be entirely successful, and the presence of counterfeit medicines may continue to increase. RISKS RELATED TO GOVERNMENT REGULATION AND LEGAL PROCEEDINGS: PRICING AND REIMBURSEMENT U. S. and international governmental regulations that mandate price controls or limitations on patient access to our products **, create coverage criteria** or establish prices paid by government entities or programs for our products impact our business, and our future results could be adversely affected by changes in such regulations or policies. ~~The~~ **In addition to the recent expansion of price controls in the U. S. in the IRA, the** adoption of restrictive **coverage policies and** price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate **coverage and** pricing could also adversely impact revenue. We expect pricing pressures **and other cost containment measures for drugs and vaccines** will continue globally. In the U. S., pharmaceutical product pricing is subject to government and public scrutiny and calls for reform, and many of our products are subject to increasing pricing pressures as a result. We expect to see continued focus by the ~~Federal government~~ **U. S. Congress and the Biden Administration** on regulating pricing ~~which could result in legislative and~~ **access regulatory changes designed to** ~~medicine control costs~~ **medicine control costs**. For example, in August 2022, the ~~drug pricing provisions of the IRA was~~ **drug pricing provisions of the IRA** ~~was~~ **were** signed into law, which, among other things, ~~requires~~ **require** manufacturers of certain drugs **, including Pfizer,** to engage in price negotiations with Medicare **which will permit the CMS to set a maximum fair price for selected drugs** ~~imposes~~ **impose** rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation, and ~~replaces~~ **replace** the Part D coverage gap discount program with a new discounting program. **The drug pricing provisions of the IRA began to be implemented in 2022 and implementation efforts are expected to continue over the next several years. In August 2023, the Biden Administration unveiled the first round of medicines subject to the Medicare Drug Pricing Negotiation Program, which included Eliquis. CMS will establish a maximum fair price for Eliquis that will be in effect in 2026. That maximum fair price will be required to be offered to all Medicare beneficiaries and to covered entities participating in the 340B Program if lower than the 340B price. Health plans may also require rebates in addition to the maximum fair price for preferred placement on a Medicare plan formulary. The Medicare Drug Price Negotiation Program is currently subject to legal challenges and therefore, the outcome of the 340B Program remains uncertain. We continue to evaluate the impact of the IRA on our business, operations, financial condition and results as the full effect of the IRA on our business and the pharmaceutical industry remains uncertain. Payors may promote generic drugs and**

**biosimilars more aggressively to generate savings and attempt to stimulate additional price competition. In addition, we expect that consolidation and integration among pharmacy chains, wholesalers and PBMs will increase pricing pressures in the industry.** Some states have implemented, and others are considering, patient access constraints or cost cutting under **state regulated programs including** the Medicaid program ~~and some are considering measures that would apply to broader segments of their populations that are not Medicaid-eligible~~. State legislatures also have continued to focus on addressing drug costs, generally by increasing price transparency or **attempting to limiting --- limit** drug price increases **for state regulated insurance**. Measures to regulate prices or payment for pharmaceutical **Pfizer Inc. 2023 Form 10- K19** products, including legislation on drug importation, **such as Florida's drug importation program which was recently approved by the FDA,** could adversely affect our business. For additional information on U. S. pricing and reimbursement, see the Item 1. Business — Government Regulation and Price Constraints section ~~in this Form 10- K~~. We encounter similar regulatory and legislative issues in most other countries in which we operate. In certain markets, such as in EU member states, the U. K., Japan, China, Canada and South Korea, governments have significant power as large single **payers payors** to regulate prices, access criteria, or impose other means of cost control, particularly as a result of recent global financing pressures. For example, the QCE and VBP tender process in China has resulted in significant price cuts for off- patent medicines **!** **Additionally, in the EU, the EC proposed the largest reform to drug pricing and access in 20 years, which if enacted would change regulatory exclusivity for our products**. For additional information regarding these government initiatives, see the Item 1. Business — Government Regulation and Price Constraints section ~~in this Form 10- K~~. We anticipate that these and similar initiatives will continue to increase pricing **and access** pressures **globally in China and elsewhere in the future**. In addition, in many countries, with respect to our vaccines, we participate in a tender process for selection in national immunization programs. Failure to secure participation in national immunization programs or to obtain acceptable pricing in the tender process could adversely affect our business. ~~We also Pricing pressures have been, and we~~ anticipate pricing pressures will **continue to** be **,** amplified by COVID- 19 induced budget deficits and focus on pricing for COVID- 19 treatments and vaccines. U. S. HEALTHCARE REGULATION The U. S. healthcare industry is highly regulated and subject to frequent and substantial changes. Any significant **additional** efforts at the U. S. federal or state levels to reform the healthcare system by changing the way healthcare is provided or funded could have a material impact on us. For additional information on U. S. healthcare regulation, see the Item 1. Business — Government Regulation and Price Constraints section ~~in this Form 10- K~~. Other U. S. federal or state legislative or regulatory action and / or policy efforts could adversely affect our business, including, among others, general budget control actions, changes in patent laws, the importation of prescription drugs to the U. S. at prices that are regulated by foreign governments, revisions to reimbursement of biopharmaceuticals under government programs that could reference international prices or require new discounts, limitations on interactions with healthcare professionals and other industry stakeholders, or the use of comparative effectiveness methodologies that could be implemented in a manner that focuses primarily on cost differences and minimizes the therapeutic differences among pharmaceutical products and restricts access to innovative medicines. ~~A~~ **Any additional** reduction of U. S. federal spending on entitlement programs **beyond the IRA,** including Medicare and Medicaid, may affect payment for our products or services provided using our products. Any other significant spending reductions or cost controls affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented could have an adverse impact on our results of operations **.** **The IRA will be implemented largely through government guidance and as its effect on Medicare and commercial markets evolve, we will continue to evaluate the potential impacts to our business. We expect additional cost containment measures at both the federal and state levels as efforts to reduce drug costs continue. Further, commercial payors often follow Medicare coverage policy and payment limitations when setting their own payment rates. Any reduction in cost or other containment measures may similarly be adopted by commercial plans. Coverage policies and reimbursement rates for commercial plans may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products, less favorable coverage policies and reimbursement rates may be implemented in the future**. DEVELOPMENT, REGULATORY APPROVAL AND MARKETING OF PRODUCTS The discovery and development of drugs, vaccines and biological products are time consuming, costly and unpredictable. The outcome is inherently uncertain and involves a high degree of risk due to the following factors, among others: • The process from early discovery to design and adequate implementation of clinical trials to regulatory approval can take many years **and have high costs.** • **We may have difficulties recruiting and enrolling patients for clinical trials on a consistent basis**. • Product candidates can and do fail at any stage of the process, including as the result of unfavorable pre- clinical and clinical trial results, or unfavorable new pre- clinical or clinical data and further analyses of existing pre- clinical or clinical data, including results that may not support further clinical development of the product candidate or indication. • We may need to amend our clinical trial protocols or conduct additional clinical trials under certain circumstances, for example, to further assess appropriate dosage or collect additional safety data. • We may not be able to meet anticipated pre- clinical or clinical endpoints, commencement and / or completion dates for our pre- clinical or clinical trials, regulatory submission dates, regulatory approval dates and / or launch dates. • We may not be able to successfully address all the comments received from regulatory authorities such as the FDA and the EMA, or be able to obtain approval for new products and indications from regulators. Regulatory approvals of our products depend on myriad factors, including regulatory determinations as to the product's safety and efficacy. In the context of public health emergencies like the COVID- 19 pandemic, regulators evaluate various factors and criteria to potentially allow for marketing authorization on an emergency or conditional basis. Additionally, clinical trial and other product data are subject to differing interpretations and assessments by regulatory authorities. As a result of regulatory interpretations and assessments or other developments that **may** occur during the review process, **and or** even after a product is authorized or approved for marketing, a product's commercial potential could be adversely affected by potential emerging concerns or regulatory decisions regarding or impacting **the scope of indicated patient populations,** labeling or marketing, manufacturing processes, safety **issues** and / or other matters, including

decisions relating to emerging developments regarding potential product impurities. ~~Pfizer Inc.~~ **Also, certain of our products have received and may in the future receive approvals under accelerated approval pathways where continued approval may be contingent upon confirmatory studies demonstrating the anticipated clinical benefit and / or safety profile.** 2022 Form 10-K17-We may not be able to receive or maintain favorable recommendations by technical or advisory committees, such as the ACIP or ~~any~~ **an** FDA Advisory Committee ~~that may be convened to review our applications such as EUAs, NDAs or BLAs~~, which may impact the **availability or commercial** potential marketing and use of our products **and product candidates**. Further, claims and concerns that may arise regarding the safety and **/ or** efficacy of in- line products and product candidates can negatively impact **current or future** product sales **, as applicable**, and potentially lead to product recalls or withdrawals, including regulator- directed risk evaluations and assessments, and / or consumer fraud, product liability and other litigation and claims. ~~Further regulatory~~ **Regulatory agency** requirements may **also** result in a more challenging, expensive and lengthy regulatory approval process than anticipated due to requests for, among other things, additional or more extensive clinical trials prior **Pfizer Inc. 2023 Form 10- K20** to granting approval, or increased post- approval requirements. For these and other reasons discussed in this Risk Factors section, we may not obtain the approvals we expect within the timeframe we anticipate, or at all. POST- AUTHORIZATION / APPROVAL DATA As a condition to granting marketing authorization or approval of a product, the FDA may require **, or the sponsor may voluntarily agree to undertake, post- marketing commitments such as additional clinical trials or other studies.** The results generated in these trials **have in the past impacted certain of our products and** could **impact our products in the future, such as by result resulting** in the loss of marketing approval, changes in labeling, and / or new or increased concerns about ~~the side effects,~~ **safety and / or** efficacy ~~or safety,~~ **including newly discovered adverse events**. Regulatory agencies in countries outside the U. S. often have similar regulations and may impose comparable requirements **, although there are differences between the U. S., the EU and other international regulatory requirements, which may contribute to inconsistency or uncertainty in the marketability of our products across different jurisdictions**. Post- marketing studies and clinical trials, whether conducted by us or by others, whether mandated by regulatory agencies or conducted voluntarily, and other emerging data about products, such as adverse event reports, may also adversely affect the availability or commercial potential of our products. Further, if safety or efficacy concerns are raised about a product in the same class as one of our products, those concerns could implicate the entire class; and this, in turn, could have an adverse impact on the availability or commercial viability of our product (s) as well as other products in the class. The potential regulatory and commercial implications of post- marketing study results typically cannot immediately be determined. ~~For example, in December 2021, in light of the results from the completed required postmarketing safety study of Xeljanz, ORAL Surveillance (A3921133), the U. S. label for Xeljanz was revised. In addition, in November 2022, the EMA concluded their assessment of JAK inhibitors authorized for inflammatory diseases in the EU, including Xeljanz and Cibinqo, and recommended that risk minimization measures, including special warnings and precautions for use, should be revised and harmonized for all such JAK inhibitors. The resulting label changes are expected to be finalized in the first quarter of 2023. We continue to work with regulatory agencies worldwide to review the full results and analyses of ORAL Surveillance and their impact on product labeling.~~ The terms of our EUA for Comirnaty require that we conduct post- observational studies to evaluate the association between the Pfizer- BioNTech ~~Covid~~ **COVID - 19 Vaccine (Original monovalent)** **and Pfizer- BioNTech COVID- 19 Vaccine, Bivalent** **, and the Pfizer- BioNTech COVID- 19 Vaccine (2023- 2024 Formula)** **, and a pre- specified list of adverse events of special interest, including myocarditis and pericarditis, along with deaths and hospitalizations, and severe COVID- 19.** The required study populations include individuals specified in our ~~December~~ **September 2022- 2023** authorization letter (reissued) as well as populations of interest, such as healthcare workers, pregnant women, immunocompromised individuals and subpopulations with specific comorbidities. Additionally, in relation to the FDA approval for Comirnaty, we are required to complete certain postmarketing study requirements and commitments through 2024 and beyond. ~~The terms of our~~ **In the FDA' s revision to the** EUA for Paxlovid **, the FDA removed the post- authorization requirements as they were addressed as a post- marketing commitment associated with the approval of the Paxlovid NDA. The terms of our Paxlovid EUA had previously require required** monitoring of a genomic database (s) for the emergence of global viral variants of SARS- CoV- 2 and providing reports to the FDA on a monthly basis summarizing any findings. Also, the FDA ~~may require~~ **required** Pfizer to assess the activity of the authorized Paxlovid against any global SARS- CoV- 2 variant (s) of interest and complete certain other analyses and studies as identified in our October 2022 EUA. LEGAL MATTERS We are and may be involved in various legal proceedings, including patent litigation, product liability and other product- related litigation, including personal injury, consumer, off- label promotion, securities, antitrust and breach of contract claims, commercial and other asserted and unasserted matters, environmental, government and tax investigations, employment, tax litigation and other legal proceedings that arise from time to time in the ordinary course of our business. Litigation is inherently unpredictable, and excessive verdicts do occur. Although we believe that our claims and defenses in matters in which we are a defendant are substantial, we **have in the past and** could in the future incur judgments, enter into settlements or revise our expectations regarding the outcome of certain matters, and such developments could have a material adverse effect on our results of operations. Claims against our patents include challenges to the coverage and / or validity of our patents on various products or processes. There can be no assurance as to the outcome of these matters, and a loss in any of these cases could result in a loss of patent protection for the product at issue, which could lead to a significant loss of sales of that product and could materially affect future results of operations. We are also involved in government investigations that arise in the ordinary course of our business. There continues to be a significant volume of government investigations and litigation against companies operating in our industry, both in the U. S. and around the world. Government investigations and actions **have and** could result in substantial criminal and civil fines and / or criminal charges, limitations on our ability to conduct business in applicable jurisdictions, corporate integrity or deferred prosecution agreements and other disciplinary actions, as well as reputational harm, including as a result of increased public interest in the matter. In addition, in a qui tam lawsuit in which the government declines to intervene, the relator may still pursue

a suit for the recovery of civil damages and penalties on behalf of the government. Our sales and marketing activities, the pricing of our products and other aspects of our business are subject to extensive regulation under the FFDCA, the Medicaid Drug Rebate Program, the FCPA and other federal and state statutes, including those discussed elsewhere in this Form 10-K, as well as the Anti-Kickback Statute, anti-bribery laws, the False Claims Act, and similar laws in international jurisdictions. In addition to the potential for changes to relevant laws, the compliance and enforcement landscape is informed by government litigation, settlement precedent, advisory opinions, and special fraud alerts. Our approach to certain practices may evolve over time in light of these types of developments. Requirements or industry standards in the U. S. and certain jurisdictions abroad require pharmaceutical manufacturers to track and disclose financial interactions with healthcare professionals and healthcare providers and can increase government and public scrutiny of such financial interactions. If an interaction is found to be improper, government enforcement actions and penalties could result. Like many companies in our industry, we have from time-to-time received, and may receive in the future, inquiries and subpoenas and other types of information demands from government authorities. In addition, we have been subject to claims and other actions related to our business activities, brought by governmental authorities, as well as consumers and private payers-payors. In some instances, we have incurred significant expense, civil payments, fines and other adverse consequences as a result of these claims, actions and inquiries. Such claims, actions and inquiries may relate to alleged non-compliance with laws and regulations associated with the dissemination of product (approved and unapproved) information, potentially resulting in government enforcement action and reputational damage. This risk may be heightened by digital marketing, including social media, mobile applications and blogger outreach. In connection with the resolution of a U. S. government investigation concerning independent copay assistance organizations that provide financial assistance to Medicare patients, in 2018, we entered into a Corporate Integrity Agreement (CIA) with the Office of the Inspector General of the HHS (OIG), which expired in May 2023. Pfizer submitted its final annual report and is awaiting effective for a response from period of five years. In the OIG CIA, we agreed to implement and/or maintain certain compliance program elements to promote compliance with federal healthcare program requirements. Breaches of the CIA could result in severe sanctions against us. Pfizer Inc. 2022 Form 10-K18 We and certain of our subsidiaries are also subject to numerous contingencies arising in the ordinary course of business relating to legal claims and proceedings, including environmental contingencies. Amounts recorded for legal and environmental contingencies can result from a complex series of judgments about future events and uncertainties and can rely heavily on estimates and assumptions. While we have accrued for Pfizer Inc. 2023 Form 10-K21 worldwide legal liabilities, no guarantee exists that additional costs will not be incurred or additional payments will not be required beyond the amounts accrued. For additional information, including information regarding certain legal proceedings in which we are involved in, see Note 16A. RISKS RELATED TO INTELLECTUAL PROPERTY, TECHNOLOGY AND SECURITY: INTELLECTUAL PROPERTY PROTECTION Our success largely depends on our ability to market technologically competitive products. We rely and expect to continue to rely on a combination of intellectual property, including patent, trademark, trade dress, copyright, trade secret and domain name protection laws, as well as confidentiality and license agreements, to protect our intellectual property and proprietary rights. If we fail to obtain and maintain adequate intellectual property protection, we may not be able to prevent third parties from launching generic or biosimilar versions of our branded products, from using our proprietary technologies or from marketing products that are very similar or identical to ours. Our currently pending or future patent applications may not result in issued patents or be granted on a timely basis. Similarly, any term extensions that we seek may not be granted on a timely basis, if at all, and any term adjustments related to patent office delays in obtaining a patent may be reduced or eliminated entirely due to risks associated with changes in law relating to patent terms. In addition, our issued patents may not contain claims sufficiently broad to protect us against claims regarding validity, enforceability, scope and effective term made by parties with similar technologies or products or provide us with any competitive advantage, including exclusivity in a particular product area. Further, legal or regulatory action by various stakeholders or governments could potentially result in us not seeking intellectual property protection for or agreeing not to enforce or being restricted from enforcing intellectual property related to our products. The WTO continues to address the role of intellectual property in the context of the COVID-19 pandemic response. This includes the June 2022 Ministerial Decision on the Agreement on Trade-Related Aspects of Intellectual Property Rights, which seeks to make it easier for certain WTO members to issue a compulsory license on COVID-19 vaccines, and discussions continue on whether to expand that decision to COVID-19 therapeutics and diagnostics. The scope of our patent claims also may vary between countries, as individual countries have distinct patent laws, and our ability to enforce our patents depends on the laws of each country, its enforcement practices, and the extent to which certain countries engage in policies or practices that weaken a country's intellectual property framework (e. g., laws or regulations that promote or provide broad discretion to issue a compulsory license). In countries that provide some form of regulatory exclusivity, mechanisms exist permitting some form of challenge to our patents by competitors or generic drug marketers prior to or immediately following the expiration of such regulatory exclusivity, and generic companies are employing aggressive strategies, such as "at-risk" launches that challenge our patent rights. Most of the suits involve claims by generic drug manufacturers that patents covering our products, uses, processes or dosage forms are invalid and / or do not cover the product of the generic or biosimilar drug manufacturer. Independent actions have been filed alleging that our assertions of, or attempts to enforce, patent rights with respect to certain products constitute unfair competition and / or violations of antitrust laws. Such claims may also be brought as counterclaims to actions we bring to enforce our patents. We are also party to other patent damages suits in various jurisdictions pursuant to which generic drug manufacturers, payers-payors, governments or other parties are seeking damages from us for alleged delay of generic entry. We also are often involved in other proceedings, such as inter partes review, post-grant review, re-examination or opposition proceedings, before the U. S. Patent and Trademark Office, the European Patent Office, or other foreign counterparts relating to our intellectual property or the intellectual property rights of others. Also, if one of our patents or a competitors' patents is found to be invalid in such proceedings, generic or biosimilar products could be introduced into the

market resulting in the erosion of sales of our existing products. For additional information, including information regarding certain legal proceedings in which we are involved, see Note 16A1. Further, if we are unable to maintain our existing license agreements or other agreements pursuant to which third parties grant us rights to intellectual property, our operating results and financial condition could be adversely affected. We currently hold trademark registrations and have trademark applications pending in many jurisdictions, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the trademark. As our products mature, our reliance on our trademarks and trade dress to differentiate us from our competitors increases and, as a result, our business could be adversely affected if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our rights. We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants, other advisors and other third parties to execute proprietary information and confidentiality agreements upon the commencement of their relationship with us. Despite these efforts and precautions, we may be unable to prevent a third-party from copying or otherwise obtaining and using our trade secrets or our other intellectual property without authorization, and legal remedies may not adequately compensate us for the damages caused by such unauthorized use. Further, others may independently and lawfully develop substantially similar or identical products that circumvent our intellectual property by means of alternative designs or processes or otherwise.

### THIRD-PARTY INTELLECTUAL PROPERTY CLAIMS

A properly functioning intellectual property regime is essential to our business model. We are committed to respecting the valid intellectual property rights of other companies, but the patent granting process is imperfect. Accordingly, the pursuit of valid business opportunities may require us to challenge intellectual property rights held by others that we believe were improperly granted, including challenges through negotiation and litigation, and such challenges may not always be successful. Part of our business depends upon identifying biosimilar opportunities and launching products to take advantage of those opportunities, which may involve litigation, associated costs and time delays, and may ultimately not be successful. These opportunities may arise in situations where patent protection of equivalent branded products has expired or been declared invalid, or where products do not infringe the patents of others. In some circumstances we may take action, such as litigation, asserting that our products do not infringe patents of existing products or that those patents are invalid or unenforceable in order to achieve a “first-to-market” or early market position for our products. Third parties may claim that our products infringe one or more patents owned or controlled by them. Claims of intellectual property infringement can be costly and time-consuming to resolve, may delay or prevent product launches, and may result in significant royalty payments or damages or potential licensing agreements. For example, our R & D in a therapeutic area may not be first and another company or entity may have obtained relevant patents before us. We are involved in patent-related disputes with third parties over our attempts to market pharmaceutical products, including related to **Abrysvo**, **Comirnaty** and **Paxlovid**. As we expand our mRNA portfolio, such patent-related disputes may increase. Once we have final ~~Pfizer Inc. 2022 Form 10-K19~~ regulatory approval of the related products, we may decide to commercially market these products even though associated legal proceedings (including any appeals) have not been resolved (i. e., “at-risk” launch). If one of our marketed products (or a product of our **Pfizer Inc. 2023 Form 10-K22** collaboration / licensing partners **to which we have licenses or co-promotion rights**) is found to infringe valid patent rights of a third party, such third party may be awarded significant damages or royalty payments, or we may be prevented from further sales of that product. Such damages may be enhanced as much as three-fold if we or one of our subsidiaries is found to have willfully infringed valid patent rights of a third party.

### INFORMATION TECHNOLOGY AND SECURITY

Significant disruptions of IT systems or breaches of information security could adversely affect our business. We extensively rely upon sophisticated IT systems (including cloud services) to operate our business. We produce, collect, process, store and transmit large amounts of confidential information (including personal information and intellectual property), and we deploy and operate an array of technical and procedural controls to maintain the confidentiality, integrity and availability of such confidential information. ~~We The Company develops~~ **develop** and ~~operates~~ **operate** digital systems to engage patients, healthcare providers, governments, ~~payers~~ **payors** and supply chain partners to conduct business and deliver medicines, digital diagnostics, clinical trials and digital therapies. Such systems include mobile applications, wearable devices, internet websites and other digital technologies that may be targets of attack. We have outsourced significant elements of our operations, including significant elements of our IT infrastructure and, as a result, we manage relationships with many third-party providers who may or could have access to our confidential information. We rely on technology developed, supplied and / or maintained by third-parties that may make us vulnerable to “supply chain” style cyber-attacks. Further, technology and security vulnerabilities of acquisitions, business partners or third-party providers may not be identified during due diligence or soon enough to mitigate exploitation. The size and complexity of our IT and information security systems, and those of our third-party providers (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by, but not limited to, our employees, contingent workers, service providers, business partners, customers or malicious attackers. As a global pharmaceutical company, our systems and assets are the target of frequent cyber-attacks. Such cyber-attacks are of ever-increasing levels of sophistication, **including the use of adversarial artificial intelligence techniques**, and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage, extortion, property destruction and personal information theft) and expertise, including, but not limited to, organized criminal groups, “hacktivists,” nation states, employees, business partners and others. Due to the nature of some of these attacks, there is a risk that they may remain undetected for a period of time. While we have invested in the protection of data and IT and ~~develop and maintain~~ systems and controls, our efforts ~~may~~, **like those of other similar companies, have** not **always and may not in the future** prevent service interruptions, extortion, theft of confidential, personal or proprietary information, compromise of data integrity or unauthorized information disclosure. Any technology service interruption or breach of our systems could adversely affect our business operations and / or result in the loss of personal data, confidential information or intellectual property. Such incidents



could require disclosure to government authorities and / or regulators and could require notification to impacted individuals and any incident could result in financial, legal, business and reputational harm to us. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. **Artificial intelligence- based software is increasingly being used in the biopharmaceutical and global healthcare industries. As with many developing technologies, artificial intelligence- based software presents risks and challenges. For example, algorithms may be flawed; data sets may be insufficient, of poor quality, or contain biased information; and inappropriate or controversial data practices by data scientists, engineers, and end- users could impair results. If the analyses that artificial intelligence- based applications assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability and brand or reputational harm. Furthermore, use of artificial intelligence- based software may lead to the release of confidential information which may impact our ability to realize the benefits of our intellectual property.** GENERAL RISKS BUSINESS DEVELOPMENT ACTIVITIES ~~One enabler of our~~ **AND STRATEGIC GOALS We have established significant growth strategy is goals, which we plan to expand our achieve, in -line part, by not only advancing our own product pipelines and maximizing the value of our existing products and product pipeline, but also through various forms of business development activities, which can include alliances, licenses, JVs, collaborations, equity- or debt- based investments, dispositions, divestments, mergers and acquisitions. Our recent acquisition of Seagen is part of that growth plan. We view our business development activity as an enabler of our strategies and seek to generate growth by pursuing opportunities and transactions that have the potential to strengthen our business and our capabilities.** The success of our business development activities is dependent on the availability and accurate evaluation of appropriate opportunities, competition from others that are seeking similar opportunities and our ability to successfully identify, structure and execute transactions, including the ability to satisfy closing conditions in the anticipated timeframes or at all, and our ability to successfully integrate acquired businesses and develop and commercialize acquired products. Pursuing, executing and consummating these transactions may require substantial investment, which may require us to obtain additional equity or debt financing, which **has in the past and could in the future result in increased leverage and / or a downgrade of our credit ratings and could limit our ability to obtain future financing. We have incurred substantial indebtedness to fund our recent acquisition of Seagen. We financed a portion of the transaction with the proceeds from the \$ 31 billion of long- term debt issued in May 2023, plus \$ 8 billion in additional short- term indebtedness issued prior to the acquisition. The amount of debt that we have incurred could have significant consequences including, among other things, reducing our operating or financial flexibility, requiring a portion of our cash flow from operations to make interest payments and reducing the cash flow available to fund capital expenditures and other corporate purposes and to grow our business. To the extent we incur additional indebtedness or interest rates increase, these risks could increase further.** The success of our business development transactions, **including our recent acquisition of Seagen,** depends on our ability to realize the anticipated benefits of ~~the these transaction~~ **transactions** and is subject to numerous risks and uncertainties, many of which are outside of our control. Unsuccessful clinical trials, regulatory hurdles and commercialization challenges, **among other factors,** may adversely impact revenue and income contribution **from business development transactions, including** from acquired products and businesses. We may fail to generate expected revenue growth for **our existing products, product pipeline an- and contribution from these transactions or from acquired product products or business- businesses** or we may fail to achieve anticipated cost savings, **such as those expected with respect to Seagen,** within expected time frames or at all, **which may impact our ability to meet our growth objectives.** In certain transactions, we may agree to provide certain transition services for an extended period of time, which may divert our focus and resources that would otherwise be invested into maintaining or growing our business. Similarly, the accretive impact anticipated from certain transactions may not be realized or may be delayed. Integration of **these- acquired** products or businesses may result in the loss of key employees, the disruption of ongoing business, including third- party relationships, or inconsistencies in standards, controls, procedures and policies. Further, while we seek to mitigate risks and liabilities through, among other things, due diligence, we may be exposed to risks and liabilities as a result of business development transactions. There is no assurance that we will be able to acquire attractive businesses or enter into strategic business relationships on favorable terms ahead of our competitors, or that such acquisitions or strategic business development relationships will be accretive to earnings or improve our competitive position. **Pfizer Inc. 2023 Form 10- K23** Where we invest in or otherwise obtain debt or equity securities of third parties in connection with business development transactions, such as our ownership interest in Haleon, we may be unable to direct or influence the management, operational decisions and policies of such companies and the value of the acquired securities will fluctuate and may lose value. Any future distribution or sale of such securities will be subject to prevailing market conditions and other factors, including the size of our ownership stake, at the time of such distribution or sale and there is no assurance **as to the price** that such securities will ultimately be sold **at an attractive price- or that such securities will be sold** at all. **PANDEMICS Pandemics, such as the COVID- 19 has pandemic, have** impacted and may **continue to in the future** impact our business, operations and financial condition and results. ~~COVID- 19- related~~ **Related** risks and challenges for our business -include, among others: **uncertainty regarding the severity and duration of a pandemic; impacts to business operations;** decreased product demand, due to reduced new prescriptions or refills of existing prescriptions and reduced demand for **certain of our** products ; used in procedures, or as a result of unemployment or increased **costs of doing business** focus on COVID- 19 vaccination; impacts due to travel limitations and mobility restrictions in some jurisdictions-; manufacturing disruptions and delays; supply chain disruptions and shortages, including challenges related to reliance on third- party suppliers resulting in reduced availability of materials or components used in the development, manufacturing, distribution or administration of our products; **evolving macroeconomic factors** disruptions to pipeline development and clinical trials **conditions, including general economic uncertainty, unemployment rates and recessionary pressures; changes in labor markets,** including challenges related to enrolling certain clinical trials

and accruing a sufficient number of cases in certain clinical trials; challenges presented by reallocating resources to assist in responding to COVID-19; costs associated with COVID-19, including increased supply chain costs and additional R & D costs incurred in our efforts to develop Comirnaty and Paxlovid; challenges related to our business Pfizer Inc. 2022 Form 10-K20 development initiatives; interruptions or delays in the operations of regulatory authorities, which may delay potential approval of new products we are developing, potential label expansions for existing products and the launch of newly-approved products; challenges operating in a virtual or hybrid work environment; increased cyber threats and attack attempts; challenges related to our intellectual property, both domestically and internationally, including in response to any pressure, or legal or regulatory action by, various stakeholders or governments that could potentially result in us not seeking intellectual property protection for or agreeing not to enforce or being restricted from enforcing intellectual property rights related to our products, including Comirnaty and Paxlovid; challenges related to conducting oversight and monitoring of regulated activities in a virtual or hybrid environment; challenges related to our human capital and talent development; **challenges related to unknown consequences on our business performance and initiatives stemming from the substantial investment of time and other resources to vaccine mandates any potential pandemic response; increased difficulty and other challenges presented by disruptions to our normal operations in response to COVID-19, as well as uncertainties uncertainty regarding the impact predicting or estimating future performance; pace of COVID-19 pandemic recovery, disruption and government volatility within the financial or credit markets; and or our financial performance in general regulatory actions to contain the virus or control the supply of medicines and vaccines.** The extent to which COVID-19 impacts our business going forward will depend on many factors, and we have made certain assumptions regarding COVID-19 for purposes of our operational planning and financial projections, including assumptions regarding the global macroeconomic impact of COVID-19, as well as the demand, revenues, supply, contracts, **market share** and commercial markets for our **current or future** COVID-19 products, which remain dynamic. Despite careful tracking and planning, we are unable to accurately predict the extent of the impact of COVID-19 **or our COVID-19 products** on our business, operations and financial condition and results due to the uncertainty of future developments. In particular, we believe the ultimate impact on our business, operations and financial condition and results will be affected by, among other things, the emergence, infectiousness and severity of the predominant strains of the SARS-CoV-2 virus, the safety, efficacy, availability and public adherence of vaccines, boosters and treatments for COVID-19; proportion of the population that receives a vaccine or treatment for **or our** COVID-19 **products**, patient demand and market share for Comirnaty and Paxlovid, timing for delivery, and potential other amendments to the terms, of contracted doses or treatment courses to certain markets, timing and effectiveness for the expected transition to the commercial market for Comirnaty and Paxlovid, the global macroeconomic impact of COVID-19 and governmental responses or regulatory actions to contain the virus or control supply of medicines and vaccines. COVID-19 may also affect our business, operations or financial condition and results in a manner that is not presently known to us or that we currently do not consider as presenting significant risks. We also face risks and uncertainties related to our efforts to develop and commercialize our COVID-19 products, as well as challenges related to their manufacturing, supply and distribution, including, among others: • **the risk that as the market for COVID-19 products becomes more endemic and seasonal, demand for any of our COVID-19 products has and may continue to be reduced or not meet expectations, or may no longer exist, which has and may continue to lead to reduced revenues, excess inventory on-hand and / or in the channel which, for Paxlovid and Comirnaty, has resulted in significant inventory write-offs in 2023 and could continue to result in inventory write-offs or other unanticipated charges; • challenges related to the transition to the commercial market for our COVID-19 products; • uncertainties related to the public's demand for vaccines, boosters and COVID-19 treatments; • risks related to our ability to accurately forecast and achieve our revenue forecasts for Comirnaty and Paxlovid or any potential future COVID-19 vaccines or treatments; • uncertainties inherent in R & D, including the ability to meet anticipated clinical endpoints, commencement and / or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and / or launch dates, as well as risks associated with pre-clinical and clinical data (including Phase 1 / 2 / 3 or Phase 4 data for Comirnaty, ~~or any monovalent, bivalent or variant-adapted vaccine candidates or any other vaccine candidate in the BNT162 program or Paxlovid or any future COVID-19 treatment~~) in any of our studies in pediatrics, adolescents or adults or real world evidence, including the possibility of unfavorable new pre-clinical, clinical or safety data and further analyses of existing pre-clinical, clinical or safety data or further information regarding the quality of pre-clinical, clinical or safety data, including by audit or inspection; • the ability to produce comparable clinical or other results for Comirnaty, any ~~monovalent, bivalent or variant-adapted vaccine candidates~~ **candidate** or other vaccines that may result from the BNT162 program, Paxlovid or any future COVID-19 treatment or any other COVID-19 program, including the rate of effectiveness and / or efficacy, safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial for any such products and additional studies, in real-world data studies or in larger, more diverse populations following commercialization; • the ability of Comirnaty, ~~any monovalent, bivalent or variant-adapted vaccine candidates~~ or any future vaccine to prevent, or Paxlovid or any future COVID-19 treatment to be effective against, COVID-19 caused by emerging virus variants; • the risk that demand for any products may be reduced, no longer exist or not meet expectations, which may lead to excess inventory on-hand and / or in the channel or reduced revenues; • challenges related to a transition to the commercial market for any of our products; • uncertainties related to the public's adherence to vaccines, boosters and treatments; • the risk that more widespread use of Comirnaty or Paxlovid will lead to new information about efficacy, safety or other developments, including the risk of additional adverse reactions, some of which may be serious; • the risk that pre-clinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review / publication process, in the scientific community generally, and by regulatory authorities; • whether and when additional data from the BNT162 mRNA vaccine program, Paxlovid or other COVID-19 programs will be published in scientific journal publications and, if so, when and with what modifications and interpretations; • whether regulatory authorities will be satisfied with the design of and results**

from existing or future pre-clinical and clinical studies; • whether and when submissions to request emergency use or conditional marketing authorizations for Comirnaty or any future vaccines in additional populations, for a potential booster dose for Comirnaty, ~~any monovalent or bivalent vaccine candidates~~ or any potential future vaccines— **vaccine or vaccine candidates** (including potential future annual boosters or re-vaccinations), and / or biologics license and / or EUA applications or amendments to any such applications may be filed in particular jurisdictions for Comirnaty, ~~any monovalent or bivalent vaccine candidates~~ or any other potential vaccines that may arise from the BNT162 program, including a potential variant-based, higher dose, or bivalent vaccine or any other potential vaccines— **vaccine candidates**, and if obtained, whether or when such EUA or licenses, or existing EUAs, will expire or terminate; • whether and when submissions to request emergency use or conditional marketing authorizations for Paxlovid or any future COVID-19 treatment and / or any drug applications and / or EUA applications or amendments to any such applications for any indication for Paxlovid or any future COVID-19 treatment may be filed in particular jurisdictions, and if obtained, whether or when such EUA or licenses, or existing EUAs, will expire or terminate; • whether and when any application that may be pending or filed for Comirnaty, any ~~monovalent, bivalent or variant-adapted~~ vaccine candidates— **candidate** or other vaccines that may result from the BNT162 program, Paxlovid or any future COVID-19 treatment or any other COVID-19 program may be approved by particular regulatory **Pfizer Inc. 2023 Form 10-K24** authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's or drug's benefits outweigh its known risks and determination of the vaccine's or drug's efficacy and, if approved, whether it will be commercially successful; • decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and / or other matters that could affect the availability or commercial potential of ~~a any~~ vaccine or drug, including the authorization or approval of products or therapies developed by other companies; • disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers, including our relationship with BioNTech; • the risk that other companies may produce ~~superior or~~ competitive products **that may be superior in terms of efficacy, safety, affordability, convenience, or a number of other competitive factors**; Pfizer Inc. 2022 Form 10-K21 • risks related to the availability **or cost** of raw materials to manufacture or test any such products; • challenges related to our vaccine's formulation; ~~dosing schedule~~ and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by us; • challenges and risks related to medication errors such as prescribing or dispensing the wrong strength, improper dosing and self-administration errors; • the risk that we may not be able to successfully develop other vaccine formulations, booster doses or potential future **vaccines, potential combination respiratory annual boosters or re-vaccinations or new variant-based or next-generation** vaccines or next generation COVID-19 treatments; • the risk that we may not be able to recoup costs associated with our R & D and manufacturing efforts; • risks associated with any changes in the way we approach or provide research funding for the BNT162 program, Paxlovid or any other COVID-19 program; • challenges and risks associated with the pace of our development programs; • the risk that we may not be able to maintain manufacturing capacity or access to logistics or supply channels commensurate with global demand for our COVID-19 products, which would negatively impact our ability to supply our COVID-19 products within the projected time periods; • ~~risks related to our ability to achieve our revenue forecasts for Comirnaty and Paxlovid or any potential future COVID-19 vaccines or treatments~~; • whether and when additional supply or purchase agreements will be reached or existing agreements will be ~~modified completed or renegotiated~~; • uncertainties regarding the ability to obtain recommendations from vaccine or treatment advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; • pricing and access challenges for such products; • challenges related to public confidence in, or awareness of Comirnaty or Paxlovid **or any future COVID-19 product candidates**, including challenges driven by misinformation or disinformation, access, concerns about clinical data integrity, or prescriber and pharmacy education; • ~~uncertainties around future changes to applicable healthcare policies and guidelines issued by the U. S. federal government in connection with the declared termination of the federal government's COVID-19 public health emergency as of May 11, 2023~~; • trade restrictions; **and** • the risk that we may owe third-party royalties or **other adverse outcomes from existing litigation related to Comirnaty and Paxlovid, or have additional** other claims asserted related to Comirnaty or Paxlovid; **Certain of these risks** and ~~competitive developments~~ **uncertainties also apply to our COVID-19 and influenza diagnostic tests**. CLIMATE CHANGE AND SUSTAINABILITY Pfizer is subject to transitional and physical risks related to climate change. Transitional risks include, for example, a disorderly global transition away from fossil fuels that may result in increased energy prices; customer preference for low or no-carbon products; stakeholder pressure to decarbonize assets; or new legal or regulatory requirements that result in new or expanded carbon pricing, taxes, restrictions on greenhouse gas emissions, and increased greenhouse gas disclosure and transparency. These risks could increase operating costs, including the cost of our electricity and energy use, or ~~other otherwise~~ **increase** compliance costs. Physical risks to our operations include water stress and drought; flooding and storm surge; wildfires; extreme temperatures and storms, which could impact pharmaceutical production, increase costs, or disrupt supply chains of medicines for patients. **For example, our manufacturing facility in Rocky Mount, NC was damaged by a tornado in July 2023. While manufacturing has resumed, the supply of medicines impacted by the tornado is expected to be affected through 2024. For additional details on the impact of the tornado in Rocky Mount, NC, see the Overview of Our Performance, Operating Environment, Strategy and Outlook — Our Operating Environment section within MD & A.** Our supply chain is ~~likely~~ subject to these same transitional and physical risks and would likely pass along any increased costs to us. ~~We do not anticipate that these risks will have a material financial impact to the company in the near term.~~ In June 2022, Pfizer established our fourth consecutive greenhouse gas reduction goal with new near- and long-term targets to achieve the Science Based Target Initiative's voluntary Net-Zero Standard by 2040. While we are working to develop **and implement** emission reduction plans to achieve our voluntary climate goals, various factors, including the long time horizons and commercial availability of new technologies to enable the emission reductions, in the time and scale needed, may present inherent risk in our ability to meet these goals. Additionally, success may depend on the actions of governments and third parties

and may require, among other things, significant capital investment; ~~research and development~~ **R & D**; and government policies and incentives to foster innovation and reduce costs of technologies that may not currently exist or be available at scale. Governmental authorities, non- governmental organizations, customers, investors, employees, and other stakeholders are increasingly sensitive to ESG matters, such as equitable access to medicines and vaccines, product quality and safety, diversity, equity and inclusion, environmental stewardship, support for local communities, value chain environmental and social due diligence, corporate governance and transparency, and addressing human capital factors in our operations. In addition, governments and the public expect companies like us to report on our business practices with respect to human rights, responsible sourcing and environmental impact, as well as the actions of our third- party contractors and suppliers around the world. This focus on ESG matters may lead to new expectations or requirements that could result in increased costs associated with research, development, manufacture, or distribution of our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for companies to establish validated Net Zero targets or offer more sustainable products. While we strive to improve our ESG performance and meet our voluntary goals, if we do not meet, or are perceived not to meet, our goals or other stakeholder expectations in key ESG areas, we risk negative stakeholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, reduced demand for our products or other negative impacts on our business and operations. While we monitor a broad range of ESG matters, we cannot be certain that we will manage such matters successfully, or that we will successfully meet the expectations of investors, employees, consumers, governments and other stakeholders. **Pfizer Inc. 2023 Form 10- K25** MARKET FLUCTUATIONS IN OUR EQUITY AND OTHER INVESTMENTS Changes in the fair value of certain equity investments **that are need to be** recognized in net income ~~that~~ may result in increased volatility of our income. ~~See~~ **For additional information, see** Note 4 and the Analysis of Financial Condition, Liquidity, Capital Resources and Market Risk section within MD & A. Our pension benefit obligations and postretirement benefit obligations are subject to volatility from changes in the fair value of equity investments and other investment risk in the assets funding these plans ~~. For additional information, see~~ **as well as changes in the appropriate discount rate. See** the Significant Accounting Policies and Application of Critical Accounting Estimates and Assumptions — Benefit Plans section within MD & A and Note 11. ~~Pfizer Inc. 2022 Form 10- K22~~ COST AND EXPENSE CONTROL AND NONORDINARY EVENTS Growth in costs and expenses, changes in product and geographic mix and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product withdrawals, recalls and other unusual events that could result from evolving business strategies, evaluation of asset realization and organizational restructuring could adversely affect future results. Such risks and uncertainties include, in particular, our ability to realize the projected benefits of our cost- reduction and productivity initiatives, **including our enterprise- wide cost realignment program**, other corporate strategic initiatives and any acquisitions, divestitures or other initiatives, as well as potential disruption of ongoing business , **such as potential impacts on our ability to deliver on our pipeline as planned. Additionally, as a result of these initiatives, we may experience a loss of continuity, loss of accumulated knowledge or intellectual property and / or inefficiency, adverse effects on employee morale, loss of key employees and / or other retention issues during transitional periods. Reorganizations and restructurings can require a significant amount of time and focus, which may divert attention from operating and growing our business. If we fail to achieve some or all of the expected benefits of restructuring, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows**. INTANGIBLE ASSETS, GOODWILL AND EQUITY- METHOD INVESTMENTS Our consolidated balance sheet contains significant amounts of intangible assets, including IPR & D and goodwill. For IPR & D assets, the risk of failure is significant, and there can be no certainty that these assets ultimately will yield successful products. Our ability to realize value on these significant investments is often contingent upon, among other things, regulatory approvals and market acceptance. As such, IPR & D assets may become impaired and / or be written off in the future if the associated R & D effort is abandoned or is curtailed. **See Note 4 for a discussion of recent impairments of IPR & D assets**. For goodwill, all reporting units can confront events and circumstances that can lead to a goodwill impairment charge such as, among other things, unanticipated competition, an adverse action or assessment by a regulator, a significant adverse change in legal matters or in the business climate and / or a failure to replace the contributions of products that lose exclusivity. Our other intangible assets, including developed technology rights and brands, face similar risks for impairment. Our equity- method investments may also be subject to impairment charges that may result from the occurrence of unexpected adverse events or management decisions that impact our estimates of expected cash flows to be generated from these investments. We may recognize impairment charges as a result of a weak economic environment, events related to particular customers or asset types, challenging market conditions or decisions by management. Any such impairment charge of our intangible assets, goodwill and equity- method investments may be significant. For additional details, see the Significant Accounting Policies and Application of Critical Accounting Estimates and Assumptions — Asset Impairments section within MD & A. CHANGES IN LAWS AND ACCOUNTING STANDARDS Our future results could be adversely affected by changes in laws and regulations or their interpretation, including, among others, changes in accounting standards, tax laws and regulations internationally and in the U. S. (including, among other things, the ~~recently enacted~~ IRA, changes in laws and regulations or their interpretation, including, among others, the adoption of global minimum taxation requirements outside the U. S. **generally effective in most jurisdictions since January 1, 2024** and potential changes to existing tax law by the current U. S. Presidential administration and Congress , **including the proposed “ Tax Relief for American Families and Workers Act of 2024 ”** ), competition laws, privacy laws and environmental laws in the U. S. and other countries. For additional information on changes in tax laws or rates or accounting standards, see the Provision / (Benefit) for Taxes on Income and New Accounting Standards sections within MD & A and Note 1B. **ITEM 1C. CYBERSECURITY** Managing cybersecurity risk is a crucial part of our overall strategy for safely operating our business. We incorporate cybersecurity practices into our Enterprise Risk Management (ERM) approach, which is **subject to oversight by our BOD. Our cybersecurity policies and practices are aligned with relevant industry standards.**

Consistent with our overall ERM program and practices, our cybersecurity program includes:

- **Vigilance:** We maintain a global cybersecurity operation that endeavors to detect, prevent, contain, and respond to cybersecurity threats and incidents in a prompt and effective manner with the goal of minimizing business disruptions.
- **External Collaboration:** We collaborate with public and private entities, including intelligence and law enforcement agencies, industry groups and third- party service providers to identify, assess and mitigate cybersecurity risks.
- **Systems Safeguards:** We deploy technical safeguards that are designed to protect our information systems, products, operations and sensitive information from cybersecurity threats. These include firewalls, intrusion prevention and detection systems, disaster recovery capabilities, malware and ransomware prevention, access controls and data protection. We continuously conduct vulnerability assessments to identify new risks and periodically test the efficacy of our safeguards through both internal and external penetration tests.
- **Education:** We provide periodic training for all personnel regarding cybersecurity threats, with such training appropriate to the roles, responsibilities and access of the relevant Company personnel. Our policies require all workers to report any real or suspected cybersecurity events.
- **Supplier Ecosystem Management:** We extend our cybersecurity management control expectations to our supply chain ecosystem, as applicable. This includes identifying cybersecurity risks presented by third parties.
- **Incident Response Planning:** We have established, and maintain and periodically test, incident response plans that direct our response to cybersecurity events and incidents. Such plans include the protocol by which material incidents would be communicated to executive management, our BOD, external regulators and shareholders.
- **Enterprise- Wide Coordination:** We engage experts from across the Company to identify emerging risks and respond to cybersecurity threats. This cross- functional approach includes personnel from our R & D, manufacturing, commercial, technology, legal, compliance, internal audit and other business functions.

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- **Governance:** Our BOD' s oversight of cybersecurity risk management is led by the Audit Committee, which oversees our ERM program. Cybersecurity threats, risks and mitigation are periodically reviewed by the Audit Committee and such reviews include both internal and independent assessment of risks, controls and effectiveness. Our risk assessment efforts have indicated that we are a target for theft of intellectual property, financial resources, personal information, and trade secrets from a wide range of actors including nation states, organized crime, malicious insiders and activists. The impacts of attacks, abuse and misuse of Pfizer' s systems and information include, without limitation, loss of assets, operational disruption and damage to Pfizer' s reputation. A key element of managing cybersecurity risk is the ongoing assessment and testing of our processes and practices through auditing, assessments, drills and other exercises focused on evaluating the sufficiency and effectiveness of our risk mitigation. We regularly engage third parties to perform assessments of our cybersecurity measures, including information security maturity assessments and independent reviews of our information security control environment and operating effectiveness. Certain results of such assessments and reviews are reported to the Audit Committee and the BOD, as appropriate, and we make adjustments to our cybersecurity processes and practices as necessary based on the information provided by the third- party assessments and reviews. The Audit Committee oversees cybersecurity risk management, including the policies, processes and practices that management implements to prevent, detect and address risks from cybersecurity threats. The Audit Committee receives regular briefings on cybersecurity risks and risk management practices, including, for example, recent developments in the external cybersecurity threat landscape, evolving standards, vulnerability assessments, third- party and independent reviews, technological trends and considerations arising from our supplier ecosystem. The Audit Committee may also promptly receive information regarding any material cybersecurity incident that may occur, including any ongoing updates regarding the same. The Audit Committee periodically discusses our approach to cybersecurity risk management with our Chief Information Security Officer (CISO). Our CISO is a member of our management team who is principally responsible for overseeing our cybersecurity risk management program, in partnership with other business leaders across the Company. The CISO works in coordination with other members of the management team, including, among others, the Chief Digital Officer, the Chief Financial Officer, the Chief Compliance and Risk Officer and the General Counsel and their designees. We believe our business leaders have the appropriate expertise, background and depth of experience to manage risks arising from cybersecurity threats. Our CISO, along with leaders from our privacy and corporate compliance functions, collaborate to implement a program designed to manage our exposure to cybersecurity risks and to promptly respond to cybersecurity incidents. Prompt response to incidents is delivered by multi- disciplinary teams in accordance with our incident response plan. Through ongoing communications with these teams during incidents, the CISO monitors the triage, mitigation and remediation of cybersecurity incidents, and reports such incidents to executive management, the Audit Committee and other Pfizer colleagues in accordance with our cybersecurity policies and procedures, as is appropriate. As of the date of this Form 10- K, we are not aware of any cybersecurity incidents that have materially affected or are reasonably likely to materially affect the Company, including our business strategy, results of operations, or financial condition at this time. For further discussion of the risks associated with cybersecurity incidents, see the Item 1A. Risk Factors — Information Technology and Security section in this Form 10- K.

ITEM 2. PROPERTIES