Risk Factors Comparison 2025-02-19 to 2024-02-21 Form: 10-K

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In addition to the other information contained in this Annual Report on Form 10- K, the following risk factors should be considered carefully in evaluating our company. It is possible that our business, financial condition, liquidity, cash flows, results of operations, reputation, and prospects could be materially adversely affected by any of these risks. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could also adversely affect our business, financial condition, liquidity, cash flows, results of operations, reputation, and prospects. Risks Related to Our Business and Industry • Pharmaceutical research and development is very costly and highly uncertain; we may not succeed in developing, licensing, or acquiring commercially successful products sufficient in number or value to replace revenues of products that have lost or will lose intellectual property protection or are displaced by competing products or therapies. There are many difficulties and uncertainties inherent in pharmaceutical research and development, the introduction of new products and indications, business development activities to enhance or refine our product pipeline, and commercialization of our products. There is a high rate of failure inherent in drug discovery and development. To bring a product from the discovery phase to market takes considerable time and entails significant cost. Failure can occur at any point in the process, including in later stages after substantial investment **and following meaningful cost for manufacturing capabilities and inventory to prepare for launch** . As a result, ~~most~~ **a significant portion of** funds invested in research and development programs will not generate **direct** financial returns. New product candidates that appear promising in development or prior to being acquired may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain or maintain necessary regulatory approvals or payer reimbursement or coverage, failure to obtain placement on guidelines or recommendations published by third- party organizations that are commensurate with clinical data, the application of pricing controls, limited scope of approved uses, label changes, changes in the relevant treatment standards or the availability of newer, better, or more cost- effective competitive products, difficulty or excessive costs to manufacture, insufficient infrastructure to support detection, diagnostic or other requisites for treatment, ineffectiveness in ~~reaching~~ **connecting with** healthcare professionals, including digitally **through** ~~given the increase in~~ virtual engagements, or infringement of the patents or intellectual property rights of others. We may also fail to allocate research and development resources efficiently, fail to pursue or invest sufficiently in product candidates or indications that may have been successful, or fail to optimally balance trial design, conduct, and speed to accomplish desired outcomes. Regulatory agencies establish high hurdles for the efficacy and safety of new products and indications. Delay, uncertainty, unpredictability, and inconsistency in drug approval processes across markets and agencies can result in delays in product launches, lost market opportunities, impairment of inventories, and other negative impacts. In addition, it can be very difficult to predict revenue growth rates of, or variability in demand for, new **or future** products and indications, which in some cases leads to difficulty meeting product demand or, on the other hand **, lower volume growth** , excess inventory and related financial charges. We cannot state with certainty when or whether our products and indications now under development will be approved or launched; whether, if initially granted, such approval will be maintained; whether we will be able to develop, license, or otherwise acquire additional product candidates, indications **,** or products; or whether our products and indications, once launched, will be commercially successful. Through internal innovation and business development we must maintain a ~~continuous~~ flow of successful ~~new~~ products and indications or line extensions sufficient both to cover our substantial research and development costs and investments and to replace revenues that are lost as profitable products become subject to pricing controls, lose intellectual property exclusivity, or are displaced by competing products or therapies. Failure to timely replenish our product portfolio and pipeline would have a material adverse effect on our business, results of operations, cash flows, and financial position. Our dependence on, or focus in, one or more key products or product classes ~~may exacerbate~~ **exacerbates** this risk. In addition, the growth of our business and revenue base increases the risk that products developed or acquired by us may not provide adequate value to sustain further long- term growth. We engage in various forms of business development activities to enhance or refine our product pipeline, including licensing arrangements, co-development agreements, co- promotion arrangements, distribution and promotion agreements, joint ventures, acquisitions, equity investments, and divestitures. There are substantial risks associated with identifying successful business development targets and consummating related transactions. ~~Increased~~ **Continued regulatory** focus on business combinations in our industry, including by the Federal Trade Commission and competition authorities in Europe and other jurisdictions, and heightened competition for attractive targets has and could continue to delay, jeopardize, or increase the costs of our business development activities. In addition, failures or difficulties in integrating or retaining new personnel or the operations of the businesses, products, or assets we acquire (including related technology, commercial operations, compliance programs, information security, manufacturing, distribution, and general business operations and procedures) may affect our ability to realize the expected benefits of business development transactions and may result in our incurrence of substantial asset impairment or restructuring charges. We also may fail to generate the expected revenue and pipeline enhancement from business development activities due to limited diligence opportunities, unsuccessful clinical trials, issues related to the quality, integrity, or broad applicability of data, regulatory impediments, and manufacturing or commercialization challenges. Additionally, business development activity focused on new modalities may entail additional risks and costs. ~~Accordingly, business~~ **Business** development transactions may not be completed in a timely manner (if at all), may not result in successful development outcomes or successful commercialization of any product, may give rise to legal proceedings or regulatory scrutiny, and may result in charges that negatively impact our financial position or results of operations in any given period. See Item 1," Business

— Research and Development — Phases of New Drug Development **,** " ~~and~~ Item 7," Management' s Discussion and Analysis — Executive Overview — **Clinical Development** ~~Late- Stage~~ Pipeline **" and Item 8," Financial Statements and Supplementary Data — Note 6: Inventories** ," for more details about our current product pipeline. • We and our products face intense competition **, including** from multinational pharmaceutical companies, biotechnology companies, and lower- cost generic and biosimilar manufacturers, and such competition could have a material adverse effect on our business. We compete with a large number of multinational pharmaceutical companies, biotechnology companies, and generic pharmaceutical companies and, in many cases, our products compete against the leading products of one or more of our competitors. To compete successfully, we must continue to deliver ~~to the market~~ innovative, cost- effective products through internal innovation or business development that meet important medical needs, provide improved outcomes **and a positive consumer experience** for patients, and deliver value to payers. Our product revenues and prospects are adversely affected by **patient access issues,** the introduction by competitors of branded products that are first to market, have better marketplace access, have greater brand recognition or are perceived as superior by the marketplace, by generic or biosimilar versions of our branded products, and by generic or biosimilar versions of other products in the same therapeutic class as our branded products. Our revenues are also adversely affected by treatment innovations, including new or superior modalities, that eliminate or minimize the need for treatment with our ~~drugs~~ **existing products, and our existing products could be subject to decreased sales volumes, realized price reductions, or both. In some cases, the introduction of our own innovative products results in these adverse impacts for our preexisting products** . Regulation of generic and biosimilar products varies around the world and such regulation is complex and subject to ongoing interpretation and implementation by regulatory agencies and courts. Particularly for biosimilars, health authority guidelines and legislative actions could make it less burdensome for competitor products to enter the market and further incentivize uptake of biosimilars. Given the importance to us of marketed biologic products and those in our clinical- stage pipeline, such regulation could have a material adverse effect on our business. See Item 1," Business — Competition" and" Business — Research and Development," for more details. Alternatively, actual or perceived failure of robust generic and biosimilar competition could propel governments to adopt additional policies and legislation that threaten our intellectual property, pricing of our products, or other aspects of our business. **Our success depends on a market that is observant of intellectual property rights and regulatory requirements. Developments that undermine that landscape can significantly impact our business and reputation. For example, we have seen an increase in the production, marketing, and sale of counterfeit, misbranded, adulterated, and compounded incretins that could materially impact us. Our actions intended to stop or prevent illegal sales of such medicines may be costly or ineffective. See Item 1," Business — Government Regulation of Our Operations and Products," for additional information on market risks related to counterfeit, misbranded, adulterated, and compounded medicines. If inadequately regulated, e- commerce may increase the prevalence of dangerous counterfeit or diverted products and scams, potentially exposing patients to significant risks. Our reputation and business could suffer harm as a result of counterfeit or diverted drugs sold under our brand name, which may also impact our business and financial results.** In addition, we rely on our ability to attract, engage, and retain highly qualified and skilled scientific, technical, management, and other personnel in order to compete effectively. To continue to commercialize our products, and advance the research, development, and commercialization of additional modalities, indications, and product candidates, we have expanded, and will likely need to further expand, our workforce ~~, including in the areas of manufacturing, clinical trials management, regulatory affairs, and sales and marketing~~ , both in and outside the U. S. We continue to face intense competition for qualified individuals from numerous multinational pharmaceutical companies, biotechnology companies, academic and other research institutions, as well as employers near our manufacturing and other facilities, which has and may continue to increase our labor costs. Our ~~ability to attract and retain talent in our increasingly competitive environment is further complicated by evolving employment trends. Our~~ failure to compete effectively for talent could negatively affect sales of our current and any future approved products and indications, and could result in material financial, legal, commercial, or reputational harm to our business. • Our business is subject to increasing government price controls and other public and private restrictions on pricing, reimbursement, and access for our drugs, which could have a material adverse effect on our results of operations, reputation or business. Public and private payers continue to take aggressive steps to control their expenditures for pharmaceuticals by placing restrictions on pricing and reimbursement for, and patient access to, our medicines. These pressures have negatively affected, and ~~could~~ **we expect will** continue to negatively affect, our consolidated results of operations. Governments and private payers worldwide have intensified their scrutiny of, and actions intended to address, pricing, reimbursement, and access to pharmaceutical products and are demanding greater commercial and clinical value from pharmaceutical companies in the form of strong product differentiation and demonstrated value. We ~~have~~ **continue to** ~~experienced~~ **experience** ~~increased~~ scrutiny on the pricing of current and potential diabetes, obesity, and Alzheimer' s **disease** products due to payer concern over projected growth in these markets and, for certain of these drugs, the anticipated duration of treatment. We have also observed scrutiny of pricing and access disparities across jurisdictions. Additional policies, regulations, legislation, or enforcement, including because of the regulatory priorities of the U. S. ~~presidential administration~~ **executive branch** and regulatory authorities worldwide, could adversely impact our business and consolidated results of operations. For example, in August 2023, HHS selected Jardiance, which is part of our collaboration with Boehringer Ingelheim, as one of the first ten medicines subject to government- set prices **in Medicare** effective in 2026 **. In August 2024, HHS announced the government- set prices for these first ten medicines with Jardiance subject to a 66 % discount compared to the 2023 U. S. calendar year list price for a 30- day supply and discounts for the other nine medicines ranging from approximately 38 % to 79 % below list price** . Given our product portfolio, we expect additional ~~significant~~ products will be selected in future years, which would have the effect of accelerating revenue erosion ~~prior to exclusivity expiry~~ . The effect of reducing prices and reimbursement for certain of our products ~~would~~ **could** significantly impact our business and consolidated results of operations. Within the U. S., state level transparency initiatives, importation rules, reporting requirements, and

mandated programs, including the establishment of drug affordability boards with the power to set upper payment limits on certain drugs in state- regulated plans, have also increased administrative costs, in some cases, compromised confidential business practices and otherwise detrimentally impacted our business. Certain states have also undertaken efforts to codify 340B contract pharmacies into statute **or impose other state law mandates,** which ~~would~~ increase the cost of 340B programs **. To date, several states have passed contract pharmacy legislation, which have been subject to various legal challenges** . For more details, see Item 1," Business — Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access." Further, restrictive or unfavorable pricing, coverage, or reimbursement determinations for our medicines or product candidates by governments, regulatory agencies, courts, or private payers, including in relation to the implementation of the IRA, reference pricing, and compulsory licensing, may adversely impact our business and financial results. We continue to experience additional pricing pressures, rebates, clawbacks, and other changes in reimbursement policies and programs resulting from ~~the financial strain of the COVID- 19 pandemic,~~ periods of uneven economic growth or downturns or uncertainty, and the emergence or escalation of, and responses to, international tension and conflicts. In addition, government price reporting and payment regulations are complex, and require ongoing assessment of the methods by which we calculate and report pricing. Calculation methodologies are inherently subjective and are subject to review and challenge by government agencies. If agencies disagree with our calculations, or the methodologies and assumptions underlying them, we may need to restate previously reported data and could be subject to financial and legal liability, which may be significant. In addition, changes to calculation methodologies could adversely affect our financial position or consolidated results of operations in any given period. For more details, see Item 1," Business — Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access," Item 7," Management' s Discussion and Analysis — Executive Overview — Other Matters — Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access ~~,~~ **and Certain Other Regulatory Developments** " and Item 8," Financial Statements and Supplementary Data — Note 16: Contingencies." • Pharmaceutical products can develop safety or efficacy concerns, which could have a material adverse effect on our revenues, income, and reputation. Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of fixed duration and defined populations. After approval and launch, the products are used for longer periods of time by much larger numbers of patients, which may lead to identifying new safety or efficacy concerns. We and others (including regulatory agencies and private payers) collect extensive information on the efficacy and safety of our marketed products by continuously monitoring the use of our products in the marketplace. In addition, we or others (including our competitors, in some cases) may conduct post- marketing clinical studies on efficacy and safety of our marketed products. New safety or efficacy data ~~from both market surveillance and post- marketing clinical studies of our products or those of our competitors~~ may result in product label changes, or other measures that could reduce the product' s market acceptance and result in declining sales. Relatedly, safety or efficacy concerns raised about a product in the same class **, compounded or counterfeit versions of** ~~or~~ **our products, or products** with the same mechanism of action as one of our products or product candidates could be imputed and have an adverse impact on the availability or commercial viability of our products or approval of product candidates. Serious safety or efficacy issues that arise after product approval have, and could in the future, result in voluntary or mandatory product recalls or withdrawals from the market. Safety issues have, and could in the future, result in costly product liability claims. Any of these outcomes could result in material financial, legal, commercial, or reputational harm to our business. • We derive a significant percentage of our total revenue from relatively few products and sell our products through ~~increasingly~~ consolidated supply chain entities, which ~~may subject~~ **subjects** us to ~~, or exacerbate,~~ various risks. We derived direct product and / or ~~alliance~~ **collaboration and other** revenues of more than $ ~~2~~ **3** billion for each of **Mounjaro, Verzenio,** Trulicity, ~~Mounjaro~~ **Zepbound** , ~~Verzenio, Taltz and~~ Jardiance (including Glyxambi, Synjardy, and Trijardy XR) **, and Taltz** that collectively accounted for ~~63~~ **75** percent of our total revenues in ~~2023~~ **2024** . In particular, **Mounjaro,** Trulicity **,** and ~~Mounjaro~~ **Zepbound** accounted for ~~36~~ **48** percent of our total revenues in ~~2023~~ **2024** and we expect **cardiometabolic health** products ~~with GLP- 1 receptor agonist activity, including the recently launched Zepbound,~~ to represent a significant and growing portion of our business, revenues, and prospects. Loss of patent protection, changes in prescription rates, material product liability or pricing litigation, unexpected side effects or safety concerns, significant changes **or fluctuations** in demand, regulatory proceedings and investigations, negative publicity affecting doctor or patient confidence, pressure from existing or new competitive products, **pipeline developments by us or our competitors,** counterfeit and illegally compounded drugs, changes in labeling, pricing, and insufficient access, or **reimbursement, or actual or perceived** supply shortages or disruptions for these products or any of our other major products could materially impact our results of operations **or result in significant and sudden declines or volatility in the trading price of our common stock and market capitalization** . In addition, in the U. S., most of our products are distributed through **a limited number of** wholesalers ~~and if~~ **. If** one of these significant wholesalers ~~should encounter~~ **encounters** financial or other difficulties **or otherwise is unable to support distribution of our products** , it **could cause disruption to our supply chain** ~~might decrease the amount of business the wholesaler does with us~~ or we might be unable to timely collect the amounts that the wholesaler owes us, which could negatively impact our results of operations. See Item 1," Business — Marketing and Distribution," for more details. Challenges to U. S. retail pharmacies due to pharmacy benefit manager reimbursement pressures, among other things, have resulted in financial difficulties for some pharmacies that may impact patient experiences, lead to determinations by certain pharmacies to not carry one or more of our significant products or threaten the viability of these pharmacies, which could negatively impact our business and results of operations. Moreover, the negotiating power of health plans, managed care organizations, pharmacy benefit managers, and other supply chain entities has increased due to consolidation, regulatory, and other market impacts, and they, along with governments, increasingly employ formularies to control costs and encourage utilization of certain drugs, including through the use of formulary inclusion, or favorable formulary placement. Such stakeholders have also increasingly imposed utilization management tools to ~~favor the use of generic products or otherwise~~ limit access to our products. As these practices expand, including due to potential further consolidation of U. S.

private third- party payers, we may face difficulty in obtaining or maintaining timely or adequate pricing or formulary placement of our products. We expect that consolidation of supply chain entities will continue to increase competitive and pricing pressures on pharmaceutical manufacturers. Pharmacy benefit manager practices have come under increased scrutiny from U. S. policymakers at the federal and state level who have proposed legislation intended to address concerns regarding the impact that these intermediaries have on drug pricing and patients' out of pocket costs. If promulgated, such legislation could have resultant implications, costs, or consequences for our business and how we interact with these entities. For additional information on pricing and reimbursement for our pharmaceutical products, see Item 1," Business — U. S. Private Sector Dynamics" and" Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access — U. S." Risks Related to Our Intellectual Property • We depend on products with intellectual property protection for most of our revenues, cash flows, and earnings; the loss of effective intellectual property protection for certain of our products has resulted, and in the future is likely to continue to result, in rapid and severe declines in revenues for those products. In the ordinary course of their lifecycles, our products lose significant patent protection and / or data protection in the U. S., as well as in key jurisdictions outside the U. S., after a specified period of time. **For example, Trulicity will lose significant patent and remaining data protections in the next few years.** Some products also lose patent protection as a result of successful third- party challenges. We have faced, and remain exposed to, generic competition following the expiration or loss of such intellectual property protection. For non- biologic products, loss of exclusivity ~~(whether by expiration of legal rights or by termination thereof as a consequence of litigation)~~ typically results in the entry of one or more generic competitors, leading to a rapid and severe decline in revenues, especially in the U. S. Generic pharmaceutical companies have in some cases introduced a generic product before resolution of any related patent litigation. For biologics, loss of exclusivity may or may not result in the near- term entry of competitor versions (i. e., biosimilars) due to many factors, including development timelines, manufacturing challenges, and / or uncertainties regarding the regulatory approval pathways. **Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions.** There is no assurance that the patents we are seeking will be granted or that the patents we hold will be found valid and enforceable if challenged. **Third parties may challenge, invalidate, or circumvent our patents and patent applications relating to our products, product candidates, and technologies. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not be deemed to infringe our patents.** Moreover, patents relating to particular products, uses, formulations, or processes ~~do~~ **may** not preclude other manufacturers from employing alternative processes or marketing alternative products or formulations that compete with our patented products. Patents held by third- parties have also contributed, and may in the future contribute, to a decision by us to not pursue all potential indications for a product candidate. In addition, competitors or other third parties may assert claims that our activities infringe patents or other intellectual property rights held by them, or allege a third- party right of ownership in our existing intellectual property. See Item 7," Management' s Discussion and Analysis — Executive Overview — Other Matters — Patent Matters ~~,~~" and Item 1," Business — Patents, Trademarks, and Other Intellectual Property Rights," for more details. Patents relating to pharmaceutical products are often obtained early in the development process. Given the limited duration of patent and data ~~protection~~ **protections** , the speed with which we develop products, complete clinical testing, receive regulatory ~~approval~~ **approvals** , supply commercial ~~product~~ **products** to the market, and obtain public and private payer access are important factors in recouping our development costs and generating financial returns, particularly given regulatory and market dynamics that have and may continue to put pressure on pricing, exclusivity periods, and competition. Delays in achieving these milestones in some cases **may** ~~limits~~ **limit** our ability to capitalize on the innovative medicines that we develop or acquire. • Our long- term success depends on intellectual property protection; if our intellectual property rights are invalidated, circumvented, or weakened, our business will be adversely affected. Our long- term success depends on our ability to continually discover or acquire, develop, and commercialize innovative medicines. Without strong intellectual property protection, we would be unable to generate the returns necessary to support our significant investments in research and development, as well as the other expenditures required to bring new ~~drugs~~ **medicines** and indications to the market. Intellectual property protection varies throughout the world and is subject to change over time, depending on local laws and regulations. Changes to such laws, regulations, and enforcement practices could reduce protections for our innovative products and indications. For example, a proposal by the European Commission to revise the EU' s general pharmaceutical legislation threatens the predictability and length of certain pharmaceutical intellectual property incentives, including by **proposed** ~~a two- year reduction~~ **reductions** ~~of~~ **in** data ~~package~~ protection **periods** . Changes proposed by the USPTO and by certain bills in Congress to limit the number of, and differences between, patents obtained could also affect the scope of patent protection for our products in the U. S. In ~~addition~~ **recent years** , ~~in December 2023, the~~ U. S. **government officials have** ~~presidential administration released a~~ proposed ~~framework that would permit~~ the ~~federal government to consider the price of a drug developed using federal funds as a factor in determining whether it may~~ exercise **of** " march- in **-** rights" and ~~license it to~~ **various other measures that, if enacted, could have** a **negative impact** ~~third party to manufacture. A comment period~~ on ~~the~~ **our patent rights. If any such** ~~proposal~~ **proposals** ~~runs through February 6, 2024, and we~~ are ~~not able to predict whether a final rule will~~ **adopted, our business and results of operations could** be **adversely affected** ~~adopted in accordance with the proposed framework~~ . Also in the U. S., in addition to the process for challenging patents set forth in the BPCIA, which applies to ~~biologic~~ **biological** products, the Hatch- Waxman Act provides generic companies substantial incentives to seek to invalidate our patents covering small molecule pharmaceutical products. As a result, we expect that our U. S. patents on major pharmaceutical products, including biologics, will continue to be routinely challenged in litigation and may not be upheld. In addition, a separate IPR process currently allows competitors to seek invalidation of patents at the USPTO without the protections of the BPCIA or Hatch- Waxman Act. The use

of IPR proceedings after the institution of litigation pursuant to the BPCIA or Hatch- Waxman Act is currently a topic of debate among legislators and the future ability of our competitors to use IPR proceedings as an alternative to Hatch- Waxman Act or BPCIA litigation procedures to challenge our patents remains uncertain. The USPTO issued an interim procedure regarding the use of discretionary denials of IPR proceedings when there is parallel district court litigation. However, it is not clear how this interim procedure could affect the ability of our competitors to institute IPR proceedings after institution of litigation. If our patents are challenged through this expedited review process, even if we prevail in demonstrating the validity of our patent, our win ~~provides limited precedential value~~ **may not preclude future challenges** at the PTAB and **is** ~~no~~ **not binding on** ~~precedential value in~~ federal district ~~court~~ **courts** , meaning the same patent can be challenged by other competitors. We face many generic manufacturer challenges to our patents outside the U. S. as well. The entry of generic competitors typically results in rapid and severe declines in revenues. In addition, competitors or other third parties may claim that our activities infringe patents or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular territory or being required to pay significant damages for past infringement or royalties on future sales. In addition, intellectual property protection in certain jurisdictions ~~outside the U. S.~~ is weak and we face heightened risks to our intellectual property rights in these jurisdictions, including competition with generic or counterfeit versions of our products at or relatively shortly after launch. See Item 1," Business — Patents, Trademarks, and Other Intellectual Property Rights ~~,~~" and Item 8," Financial Statements and Supplementary Data — Note 16: Contingencies," for more details. ~~We also face challenges from the distribution of counterfeit and illegally compounded versions of our genuine drugs, including as related to our products with GLP- 1 receptor agonist activity. Counterfeits, and in some cases illegally compounded drugs, fraudulently claim to be, or claim to contain, genuine branded medicines. Counterfeit and illegally compounded drugs may not have the same safety, quality, and effectiveness as approved drugs, and may pose serious health risks to patients. Our reputation and business could suffer harm from counterfeit or illegally compounded drugs and our actions to stop or prevent illegal sales of such drugs may be costly or ineffective.~~ Risks Related to Our Operations • Failure, inadequacy, breach of, or unauthorized access to, our IT systems or those of our third- party service providers, unauthorized access to our confidential information, or violations of data protection laws, could each result in material harm to our business and reputation. Important confidential information owned by us, our business partners, or other third parties is stored in our information systems, networks, and facilities or those of third parties. This includes valuable trade secrets and intellectual property, clinical trial information, corporate strategic plans, marketing plans, customer information, and ~~personally~~ -- **personal** ~~identifiable~~ information, such as employee and patient information (collectively, confidential information). We also rely, to a large extent, on the efficient and uninterrupted operation of complex information technology systems, infrastructure, cloud technologies, and hardware (together, IT systems), some of which are within our control and some of which are within the control of third parties, to accumulate, process, store, and transmit large amounts of confidential information and other data. We are subject to a variety of evolving and developing laws and regulations around the world related to privacy, data protection, and data security. Maintaining the security, confidentiality, integrity, and availability of our IT systems and confidential information is vital to our business. Our failure, or the failure of our third- party service providers, to protect and maintain the security, confidentiality, integrity, and availability of our (or their) IT systems and confidential information and other data could significantly harm our reputation as well as result in significant costs, including those related to fines, penalties, litigation, and obligations to comply with applicable data breach laws **. A cybersecurity incident could also impose business costs through lost productivity, disruption to manufacturing, and costs to remediate and recover from the incident** . IT systems are inherently vulnerable to system inadequacies, inadequate controls or procedures, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, theft, exfiltration, ransomware, or cyber- attacks from a variety of sources, which may remain undetected for significant periods of time. From time to time, we update, transition, acquire, or expand use of our and third- party IT systems, which may result in heightened vulnerability. Some third- party IT systems that are necessary for the operation of our business processes are maintained outside of our control but would impact business operations if compromised as a result of a cyber- attack ~~. In February 2024, we completed the implementation of a new global enterprise resource planning (ERP) system, which replaced our operating and financial systems, and we recently began our post- implementation activities. We cannot assure that the ERP system and our post- implementation activities will be free of significant operating failures, service interruptions, or creation of additional vulnerabilities. See Item 9A," Controls and Procedures" for more details~~ . Vulnerabilities, inadequacies, or failures are in many cases more acute for IT systems associated with recently acquired businesses, and we may be unable to entirely address such vulnerabilities, inadequacies, or failures immediately after acquiring a business or ever. As a result, our newly acquired businesses are in some cases more vulnerable to failures, interruptions, breaches, intrusions, theft, exfiltration, or attacks. Cyber- attacks are growing in their frequency, sophistication, and intensity, and are becoming increasingly difficult to detect, mitigate, or prevent. Cyber- attacks come in many forms, including the deployment of harmful malware, exploitation of vulnerabilities (including those of third- party software or systems), denial- of- service attacks, the use of social engineering **(including phishing)** , and other means to compromise the confidentiality, integrity, and availability of IT systems, confidential information, and other data. Breaches resulting in the compromise, disruption, degradation, manipulation, loss, theft, exfiltration, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, interference with, or attack of, our IT systems, products and services, can occur in a variety of ways, including negligent or wrongful conduct by employees or others with permitted access to our systems and information, or wrongful conduct by hackers, competitors, ~~governments~~ **organized criminal groups** , nation- states, state- sponsored or affiliated groups, current or former company personnel, and other actors. Our third- party partners, including third- party providers of data hosting or cloud services, as well as suppliers, distributors, alliances, and other third parties with whom we may share data, face similar risks, which could affect us directly or indirectly. Unassociated third parties present further risks, including by propagating **and amplifying** misinformation related to our products, business, and industry, including through social media. We and others in the

healthcare industry have been and continue to be targets for cyber- attacks, and the number of threats has increased over time. Numerous ~~federal~~ **government** agencies that monitor and regulate internet and cyber- crime have issued guidance, alerts and directives warning of software vulnerabilities that require immediate patching, malicious actors targeting healthcare- related systems and nation- state sponsored hacking designed to steal valuable information. The failure, inadequacy, or breach of our IT systems or business processes **or controls or procedures** , the compromise, disruption, degradation, manipulation, loss, theft, exfiltration, destruction, or unauthorized access to, disclosure or use of, confidential information, or the unauthorized access to, disruption of, or interference with our products and services that rely on IT systems or business processes, could impair our ability to secure and maintain intellectual property rights; result in a product manufacturing interruption or failure, or in the interruption or failure of products or services that rely on IT systems or business processes; damage our operations, patient and other relationships, or reputation; undermine integration activities or otherwise delay or prevent the launch of ~~acquired~~ products; result in unfavorable clinical trial results by virtue of incorrect or unreliable data; expose us to ransom payment, other demands, or paralyze our operations; give rise to legal liability and regulatory action under data protection and privacy laws; require disclosure to government authorities and / or regulators; expose us to civil and criminal investigations; and / or cause us to lose trade secrets or other competitive advantages, which effects could endure for a long period of time. Unauthorized disclosure of personally identifiable information could further expose us to significant sanctions for violations of data privacy laws and regulations around the world, subject us to litigation, and damage public trust in our company. In addition, IT system security in jurisdictions outside the U. S. is weaker and may result in additional costs, uncertainties, and risks. We are subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer, and security of personal information. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and the subject of significant attention by regulators and private parties globally. Regulators are imposing new data privacy and security requirements, including new and greater monetary fines or penalties for privacy violations, and jurisdictions where we operate have passed, or continue to propose, data privacy legislation and / or regulations. For example, we are subject to existing laws in the EU, United Kingdom, China, and U. S., all of which provide for substantial penalties for noncompliance. Other jurisdictions where we operate have passed, or continue to propose, similar legislation and regulations. **Many jurisdictions, including the U. S., the EU, and China have passed, or expect to pass, restrictions on international data transfers. Compliance with current and future laws and regulations requires implementing potentially costly new controls and processes and may restrict certain core activities, including impacting our ability to carry out research and clinical studies across multiple geographies.** Failure to comply with these current and future laws could result in significant penalties and reputational harm and could have a material adverse effect on our business and results of operations. To date, system inadequacies, inadequate controls or procedures, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, theft, exfiltration, ransomware, cyber- attacks, and the compromise, disruption, degradation, manipulation, loss, theft, exfiltration, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, interference with, or attack of, our IT systems, products and services **that we have encountered** have not had a material impact on our business strategy, results of operations or financial condition. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, operational, legal, business, or reputational losses that may result from an interruption or breach of our IT systems. We continue to implement measures in an effort to protect, detect, respond to, **remediate,** and minimize or prevent these risks and to enhance the resiliency of our IT systems; however, these measures may not be successful, and we may fail to detect or remediate system inadequacies, inadequate controls or procedures, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, theft, exfiltration, ransomware, cyber- attacks, or other compromises of our systems. Any of these events could result in material financial, operational, legal, business, or reputational harm to our business. For a discussion of our management of cybersecurity risks, see Item 1C," Cybersecurity — Risk Management and Strategy" and" — Governance." • Manufacturing, quality, or supply chain difficulties, disruptions, or shortages could lead to product supply problems. We are ~~in~~ **continuing** the ~~midst of a~~ significant expansion of our manufacturing capabilities and substantial investment in long- term supply agreements to **fortify supply and** support ~~current and~~ anticipated demand for our products. Pharmaceutical manufacturing is complex and highly regulated. Manufacturing or quality assurance difficulties at our facilities or those of our contractors and suppliers, the failure or refusal of a supplier or contract manufacturer to supply contracted quantities **in a timely manner or at all** , or increases in demand on a supplier with constrained capacity ~~could~~ **have resulted and may in the future** result in delays and disruptions in the manufacturing, distribution, and sale of our products and / or product shortages, leading to lost revenue ~~or ,~~ reduced ~~marked~~ **market** opportunities **, and the possibility of additional market entrants** . In select cases, supply constraints may also lead to pauses, discontinuations, or other product availability issues in one or more markets, which could have a material adverse effect on our consolidated results of operations, cash flows, and reputation. Further, cost inflation and global transportation and logistics challenges, as well as tight labor markets, have caused, and in the future may cause, delays in, and / or increase costs related to, distribution of our medicines, the construction or other acquisition of additional manufacturing capacity, procurement activity, and supplier or contract manufacturer arrangements. These disruptions and challenges could result from actual or perceived quality, oversight, or regulatory compliance problems; natural disasters (including increased instances or severity of natural disasters or other events that may be due to climate change), public health outbreaks, epidemics, or pandemics; periods of uneven economic growth or downturns; emergence or escalation of, and responses to international tension and conflicts; equipment, mechanical, data, or IT system vulnerabilities, such as system inadequacies, inadequate controls or procedures, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, theft, exfiltration, ransomware or other cyber- attacks from a variety of sources; labor shortages; challenges and complexities in manufacturing new drug modalities; contractual disputes with our suppliers and contract manufacturers; vertical integration by competitors within our supply chain; or inability to obtain single- source or other

raw or intermediate materials. Regional or single source dependencies may in some cases accentuate risks related to manufacturing and supply. For example, we, and the pharmaceutical industry generally, depend on China- based ~~partners~~ **suppliers** for **portions of our supply chain, including** integral chemical synthesis, reagents, starting materials, and ingredients. Finding alternative suppliers if and as necessary due to geopolitical developments or otherwise may not be feasible or could take a significant amount of time and involve significant expense due to the nature of our products and the need to obtain regulatory approvals which would cause disruptions to patients and detrimentally impact our business. **See, Item 1A," Risk Factors — Risks Related to Our Operations — Reliance on third- party relationships and outsourcing arrangements could adversely affect our business," and" Risk Factors — Risks Related to Doing Business Internationally — Uneven economic growth or downturns or international trade and other global disruptions, geopolitical tensions, or disputes could adversely affect our business and operating results" for more details. Supply and channel dynamics in some cases also contribute to variability in financial results for our products from period to period.** Difficulties in predicting or variability in demand **and supply** for our products and those of our competitors and the very long lead times necessary for the expansion and regulatory qualification of pharmaceutical manufacturing capacity have resulted, and in the future may result, in difficulty meeting demand, or disruptions, shortages, and higher costs in the supply of, our products. For example, **at various times during 2024** ~~we have experienced challenges in meeting~~ demand for our incretin **medicines exceeded** ~~products~~ **production . While tirzepatide** ~~in recent periods, partially due to the limited availability of competitor therapies, and expect tight~~ supply **currently exceeds demand in the U. S., demand remains dynamic and could be impacted by a variety of factors. Supply considerations will continue** to ~~persist while additional manufacturing capacity is operationalized~~ **influence the timing and approach (including available presentations) of tirzepatide launches in new markets** . Despite our ongoing efforts to meet ~~significant expected~~ **projected future** demand by obtaining additional internal and contracted manufacturing capacity, there can be no assurances that such capacity increases **that we expect will be needed to meet future demand** will be realized as expected **or that we will meet demand in launched markets in the future** . Delays or challenges in operationalizing additional manufacturing capacity ~~would~~ **could** limit our ability to capitalize on demand for our products. Conversely, unexpected events that limit demand for our products **or anticipated demand for product candidates** would undermine our ability to realize the full benefit of significant capital expenditures that we have incurred, and expect to continue to incur, to augment manufacturing capacity **, may render built or in process manufacturing capacity unnecessary,** and may also subject us to contractual payment obligations, which may be significant. The foregoing risks and uncertainties could negatively impact our consolidated results of operations and reputation. See Item 1," Business — Raw Materials and Product Supply ~~,~~" and Item 7," Management' s Discussion and Analysis — Financial Condition and Liquidity **,** " for more details. • Reliance on third- party relationships and outsourcing arrangements could adversely affect our business. We rely on third parties, including suppliers, distributors, alliances, and collaborations with other pharmaceutical and biotechnology companies, and third- party service providers, for selected aspects of product and clinical development, manufacturing, commercialization, hosting of, and support for, IT systems, product distribution, and certain financial transactional processes. As examples, we outsource the day- to- day management and oversight of some of our clinical trials to contract research organizations, certain active ingredient manufacturing, finishing operations, and device or component production and assembly to contract manufacturing organizations, and the distribution of our products through logistics providers. ~~In some cases,~~ **To support anticipated demand for our current and prospective** ~~product~~ **products** ~~or indication approvals depend on~~ **, we have expanded relationships with contract manufacturing organizations and** ~~the~~ **other** ~~outcome of regulatory inspections of~~ third parties ~~on which we rely. For example,~~ in ~~September 2023, the FDA issued a complete response letter for our lebrikizumab BLA for the treatment of moderate to severe atopic dermatitis. In the letter, the FDA cited findings that arose during a multi- sponsor inspection of a third- party, contract manufacturing organization that included the monoclonal antibody drug substance for lebrikizumab. We may encounter similar difficulties in the future, which could delay or prevent~~ **recent periods** ~~product launches and otherwise negatively affect our business, results, and reputation~~ . Outsourcing involves many risks, including the risk that third parties may not perform to our standards or legal requirements ~~, including applicable requirements for diversity in clinical trials~~ ; may not produce reliable results; may not perform in a timely manner; may not maintain the confidentiality, integrity, and availability of confidential and proprietary information relating to us, our clinical trial subjects, or patients; may experience disruption or fail to perform due to IT system vulnerabilities, such as inadequacies, inadequate controls or procedures, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, theft, exfiltration, ransomware or other cyber- attacks; may be unable to satisfy their commitments to us in which case we may not be able to achieve acceptable alternative sourcing; or may fail to perform at all. The foregoing risks may be heightened in jurisdictions outside the U. S., where we may have fewer alternative providers as well as face additional costs, uncertainties, and risks. **Among other third- party providers, we, and the pharmaceutical industry generally, depend on China- based suppliers for portions of our supply chain. U. S. officials are increasingly considering legislation or other actions that are intended to limit supply chain reliance on China, including the BIOSECURE Act. In February 2025, the U. S. presidential administration imposed new tariffs on Chinese goods and China responded with tariffs on select U. S. goods. If enacted, additional measures could result in supply disruptions or delays, increase costs more significantly, or invite further retaliatory measures, any of which could negatively impact our business. See, Item 1A," Risk Factors — Risks Related to Doing Business Internationally — Uneven economic growth or downturns or international trade and other global disruptions, geopolitical tensions, or disputes could adversely affect our business and operating results" for additional information. In some cases, product or indication approvals depend on the outcome of regulatory inspections of third parties on which we rely. Third- party inspection outcomes have and may in the future delay or prevent product launches and otherwise negatively affect our business.** Failure of third parties to meet their contractual, regulatory, confidentiality, privacy, security, or other obligations to us, our clinical trial subjects, and our patients could have a material

adverse effect on our business **and could also result in non- compliance with legal or regulatory requirements or industry standards or subject us to reputational harm** . • Our use of artificial intelligence (AI) or other emerging technologies could adversely impact our business and financial results. We ~~have begun to~~ deploy AI and other emerging technologies in various facets of our operations and we continue to explore further use cases for AI. The rapid advancement of these technologies presents opportunities for us in research, manufacturing, commercialization, and other business endeavors but also entails risks, including that AI- generated content, analyses, or recommendations we utilize could be deficient, **or** that our competitors may more quickly or effectively adopt AI capabilities **. Our** ~~, or that our~~ use of AI or other emerging technologies **could also** ~~exacerbates~~ **exacerbate** regulatory, cybersecurity and other significant risks. Effective development, management, and use of AI technologies is novel and complex, and there are technical challenges associated with achieving desired levels of accuracy, efficiency, and reliability. The algorithms and models utilized in AI systems may have limitations, including biases, errors, or inability to handle certain data types or scenarios or to render explainable outputs. Furthermore, there are risks associated with the fact that the platforms providing AI models are in many cases owned and operated by emerging companies with less contractual and compliance sophistication. These factors may undermine our ability to effectively utilize AI or create competitive disadvantages should our competitors more skillfully make use of AI capabilities. Further, if we are unable to effectively manage the use of AI technologies by our employees, our confidential information, intellectual property, or reputation could be put at risk. The emergence of AI and other technologies ~~, particularly generative AI,~~ may exacerbate other risks, including those related to regulation, litigation, compliance issues, ethical concerns, confidentiality, and data privacy or security. For example, regulatory uncertainty related to AI or other emerging technologies may require significant resources to adjust business practices to comply with developing laws. Several governmental authorities have already proposed or enacted laws and other guidance governing AI, such as the ~~proposed~~ EU Artificial Intelligence Act. These and other developing obligations may prevent or make it harder for us to conduct or enhance our business using AI, or lead to regulatory fines, penalties, or other liability. Further, use of AI technologies could lead to unintended consequences, such as **data leakage, healthcare fraud and abuse,** cybersecurity **incidents** ~~risks or unintended biases~~ , ~~impact our ability to protect our confidential data and intellectual property, and expose us to~~ intellectual property infringement ~~claims by third parties~~ **, or unintended biases** . ~~Risks Related to Doing Business Internationally~~ • Uneven economic growth or downturns or international trade and other global disruptions, geopolitical tensions, or disputes could adversely affect our business and operating results. Economic slowdowns could lead to decreased utilization of our products, affecting our sales. Declining tax revenues and increased government spending on other programs attributable to uneven economic growth or downturns increase the pressure on governments to reduce healthcare spending, leading to increased control of drug prices or lower utilization. Additionally, some customers, including governments or other entities reliant upon government funding and cash- pay patients, may be unable to pay for our products fully or in a timely manner. Also, if our customers, suppliers, or collaboration partners experience financial difficulties, we could experience slower customer collections, greater bad debt expense, and performance defaults by suppliers or collaboration partners. Similarly, uneven economic growth or downturns could limit our ability to access capital markets. In addition, significant portions of our business are conducted in Europe, Asia, and other international geographies. Trade and other global disputes and interruptions, including related to tariffs, trade protection measures, import or export licensing requirements, the imposition of trade sanctions or similar restrictions by the U. S. or other governments, international tension and conflicts, as well as **economic stagnation,** cost inflation, strains on global transportation, manufacturing, and labor markets, and public health outbreaks, epidemics, or pandemics ~~, such as the COVID- 19 pandemic,~~ affect our ability to do business. **Among other risks, the use of tariffs and other trade restrictions increase costs and may impact clinical trials** ~~For~~ **or** ~~example~~ **sales of our products, or otherwise complicate aspects of our business. In particular** , tensions between the U. S. and China **, which** have **already** led to a series of tariffs and sanctions ~~being imposed by the U. S. on imports from China mainland~~ , as well as other business restrictions **, could further escalate based on additional trade restrictions or retaliation thereto. In February 2025, the U. S. presidential administration imposed new tariffs on Chinese goods and China responded with tariffs on select U. S. goods. Additionally, tariffs were proposed or threatened with respect to other jurisdictions, including Mexico, Canada and Europe** . If geopolitical tensions were to increase and disrupt our operations in, or related to, China **or other major international geographies** , such disruption would significantly impact our business. **See Item 1A," Risk Factors — Risks Related to Our Operations — Reliance on third- party relationships and outsourcing arrangements could adversely affect our business," for additional information.** As a further example, the financial impact of higher energy prices, defense spending, and ~~inflation due, in part, to~~ geopolitical and economic disruptions, has further exacerbated financial pressures on governments with single- payer or government funded healthcare systems, leading to increased impetus for increases in rebates, clawbacks, and other reforms to reimbursement systems, particularly in Europe. These and similar events have adversely affected, and may continue to adversely affect, us, our business partners, and our customers. For more details, see Item 1," Business — Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access." In addition to developments related to our business or financial results, or those of our competitors, uneven economic growth, downturns, or other negative global developments, could also undermine our growth or result in significant and sudden declines in the trading price of our common stock and market capitalization. • Changes in foreign currency rates, interest rate risks, and inflation **or deflation** affect our results of operations. As a global company, we face foreign currency risk exposure from fluctuating currency exchange rates, interest rate risk from our exposure to floating and variable interest rates, and ~~inflation risk from~~ existing and expected rates of inflation **or deflation** in the U. S. and other jurisdictions, each of which impacts our results of operations. In recent periods, significant fluctuations in currency rates and inflation have impacted our results of operations. We are a net receiver of foreign currencies, and our results of operations are adversely impacted when the U. S. dollar is strong compared to foreign currencies. Further, in the event of an extreme devaluation of local currency in a particular market in which we operate, the price of our products could become unsustainable in the relevant market. Inflationary pressures in recent periods

have also negatively impacted us and may continue to negatively impact us in various ways, including cost inflation, higher labor costs, and other higher expenses, with some of these higher expenses due in part to policy actions intended to curb inflation. See Item 7," Management' s Discussion and Analysis — Financial Condition and Liquidity" and Item 8," Financial Statements and Supplementary Data — Note 1: Summary of Significant Accounting Policies and Implementation of New Financial Accounting Standards," for more details. Risks Related to **Litigation and** Government Regulation ~~and Litigation~~ • We ~~face~~ **are party to** litigation and investigations related to our products, how we price or commercialize our products, and other aspects of our business, which could adversely affect our business, and we are self- insured for such matters. We are subject to a substantial number of claims **, litigation, and investigations** involving various current and historical products ~~, litigation,~~ and ~~investigations~~ **practices** . These claims relate to how we commercialize and / or how we price our products, ~~including relating to our 340B drug pricing program,~~ product safety, **our operations** as well as contractual matters and other disputes **. We have also filed lawsuits and taken other legal actions to protect our intellectual property and address unlawful practices** . See Item 8," Financial Statements and Supplementary Data — Note 16: Contingencies **,** " for more information on **certain matters** ~~our current product liability litigation, as well as pricing and other litigation, investigations, and inquiries~~ . Like many companies in our industry, from time to time investigations into aspects of our business include inquiries, subpoenas, and other types of information demands from government and regulatory authorities. There continues to be a significant volume of government and regulatory investigations and litigation against companies operating in our industry, as well as ~~increasingly~~ robust regulatory enforcement. Because of the nature of pharmaceutical products, we are, and could in the future become, subject to large numbers of product liability claims for our previous, current, or future products, or to further litigation or investigations, including related to product safety and pricing or other commercial practices. Some of these matters involve numerous plaintiffs and parties seeking large or indeterminate financial claims and may remain unresolved for several years. Such matters could negatively impact our reputation, affect our results of operations or require us to recognize substantial charges to resolve and, if involving marketed products, could adversely affect sales of the product and our consolidated results of operations in any given period **. Where we are the plaintiff or complainant, we may be unsuccessful in protecting our intellectual property or mitigating harm to us from unlawful practices** . Due to a very restrictive market for liability insurance, we are predominately self- insured for litigation liability losses for all of our ~~currently marketed~~ products, as well as for litigation or investigations related to our pricing practices or other similar matters. • We are subject to evolving and complex tax laws, which may result in additional liabilities and affect our results of operations. We are subject to income taxes in the U. S. and numerous other jurisdictions, and in the course of our business, we make judgments about the expected tax treatment of various transactions and events. Changes in tax laws, regulations, administrative practices, principles, disclosure obligations, and interpretations, as well as events that differ from our expectations, have affected and may adversely affect our effective tax rates, cash flows, and / or results of operations. In addition, tax authorities in the U. S. and other jurisdictions in which we do business routinely examine our tax returns and are ~~intensifying~~ **expected to increase** their scrutiny and examinations of cross- border tax issues, which could unfavorably impact our results of operations **and cash flows** . Further, actions taken with respect to tax-related matters by associations such as the Organisation for Economic Co- operation and Development **(OECD)** and the European Commission could influence tax laws in countries in which we operate, such as the ~~recent~~ enactments by both ~~the~~ EU and non- EU countries of a global minimum tax. Modifications to key elements of the U. S. or international tax framework could have a significant impact on our effective tax rate, results of operations, and cash flows. See Item 7," Management' s Discussion and Analysis — Executive Overview — Other Matters — Tax Matters" and Item 8," Financial Statements and Supplementary Data — Note 14: Income Taxes," for more details. • Regulatory compliance problems could be damaging to the company. The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to extensive scrutiny and regulation. ~~Many companies, including us, are and have been subject to investigations, litigation, and claims related to these practices asserted by governmental authorities and other parties. These investigations, litigation, and claims have resulted in substantial expense and other significant consequences. The final outcomes of such investigations, litigation, and claims include criminal charges and fines, penalties, or other monetary or non- monetary remedies, including exclusion from U. S. federal and other healthcare programs. Such investigations, litigation, and claims have intensified and may continue to intensify as a result of evolving U. S. and foreign regulatory priorities.~~ New business practices or commercial capabilities ~~may~~ subject us to additional scrutiny over compliance with applicable regulatory schemes and compliance obligations or expose us to new regulatory schemes and compliance obligations entirely. **Many companies, including us, are and have been subject to investigations, litigation, and claims related to these practices asserted by governmental authorities and other parties. These investigations, litigation, and claims have resulted in substantial expense and other significant consequences for pharmaceutical manufacturers, including criminal charges and fines, penalties, or other monetary or non- monetary remedies, including exclusion from U. S. federal and other healthcare programs. Such investigations, litigation, and claims remain intense as a result of evolving U. S. and foreign regulatory priorities.** In addition, regulatory issues **and evolving standards** concerning compliance with cGMP ~~,~~ **and** quality assurance, **including** ~~evolving standards, and~~ increased scrutiny around excipients ~~and~~ **,** potential impurities such as nitrosamines, and **chemicals important to pharmaceutical manufacturing,** ~~similar regulations and standards (and comparable foreign regulations and standards) for our products~~ in some cases lead to regulatory and legal actions, product recalls and seizures, fines and penalties, interruption of production leading to product shortages, import bans or denials of import certifications, delays or denials in new product approvals or line extensions or supplemental approvals of current products pending resolution of the issues, and reputational harm, any of which adversely affects our business. Regulatory oversight of the pharmaceutical industry entails judgment and interpretation, which can result in ~~inconsistent administration~~ **varying interpretations** of laws and regulations by health **and other** authorities **. In addition, changing political leadership, including the new presidential administration and regulatory leadership in the U. S., may propose, enact, or pursue**

policy, regulatory, and enforcement changes that create additional uncertainty for our business . Regulatory compliance and processes in jurisdictions outside the U. S. may be particularly unpredictable and result in additional costs, uncertainties, and risks. U. S. and foreign governmental authorities are actively promulgating additional regulations **and guidance** that impact many aspects of our operations. These regulations are in some cases advanced with short notice. New regulations may undermine our ability to achieve business objectives, may be costly to implement, may provide only limited time for compliance, may change accounting and reporting standards, and may carry significant penalties for non- compliance. See Item 1," Business — Government Regulation of Our Operations **and Products** ," for more details **. We rely on the FDA and other regulatory bodies for appropriate oversight, administration and enforcement across our industry, anyone marketing or purporting to market medicines, and public health. Oversight, administrative, and enforcement changes, delays, inconsistencies, lapses, and failures could materiality impact our business and reputation. See Item 1," Business — Government Regulation of Our Operations and Products," for additional information on regulatory risks, including as related to counterfeit, misbranded, adulterated, and compounded medicines** . Furthermore, there is an increased focus by foreign, federal, state, and local regulatory and legislative bodies ~~regarding environmental~~ **on legislation and** policies relating to climate change, regulating greenhouse gas emissions, carbon taxes, emissions trading schemes, sustainability, human rights and ~~equity~~ **related due diligence, workforce** matters, and disclosure regarding the foregoing, many of which may be ambiguous, inconsistent, dynamic or conflicting. We **have** ~~expect to experience~~ **experienced** increased ~~restrictions and~~ compliance costs, legal costs, and expenses related to such new or changing legal or regulatory requirements. Moreover, compliance with any such legal or regulatory requirements ~~would require~~ **requires** us to devote **time and attention, which may be** substantial **,** ~~time and attention~~ to these matters. In addition, we may still be subject to penalties or potential litigation if such laws and regulations are interpreted or applied in a manner inconsistent with our practices. Additionally, **there is** ~~we are subject to~~ increased ~~negative~~ attention from the media, stockholders, activists **, political leadership, regulatory authorities** , and other stakeholders on climate ~~change~~ , social, and **other** sustainability matters. The perception that we **or others in our industry or supply chain** have failed to act in **an appropriate** ~~a socially responsible~~ manner, whether or not valid, results in ~~adverse~~ publicity that can negatively affect our business, brand, and reputation, as well as result in increased scrutiny from **political leadership,** legislators and regulatory authorities **. For example, negative perception of inclusion initiatives, whether due to a perceived over- or under- pursuit of such initiatives, may result in issues hiring or retaining employees, as well as potential investigations, enforcement actions, litigation, reputational harm, or other adverse impacts** . Moreover, from time to time we establish and publicly announce goals **, initiatives,** and commitments, including ~~to reduce our impact~~ on **climate, social, and** ~~the~~ **other** ~~environment~~ **sustainability matters** . Our ability to achieve any **of these** stated ~~environmental, social or governance goal~~ **goals** , ~~target~~ **targets** or ~~objective~~ **objectives** is subject to numerous factors and conditions, many of which are outside our control. Examples of such factors include evolving regulatory requirements affecting sustainability standards or disclosures or imposing different requirements, ~~the availability of requisite financing,~~ and the availability of suppliers that can meet our sustainability and other goals. If we fail to achieve, are perceived to have failed or been delayed in achieving, or improperly report our progress toward achieving these goals **, initiatives,** and commitments, it could negatively affect our reputation, brand, or investor confidence, and expose us to **investigations,** enforcement actions and litigation. ~~35~~ **Conversely, our pursuit or achievement of such goals, initiatives, and commitments may not be viewed favorably by certain stakeholders and could increase scrutiny of our business, negatively affect our reputation, or expose us to investigations, enforcement actions and litigation. 36**