

Risk Factors Comparison 2024-02-12 to 2023-02-10 Form: 10-K

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Our business faces significant risks. You should carefully consider all of the information set forth in this Annual Report and in our other filings with the SEC, including the following risk factors which we face and which are faced by our industry. Our business, financial condition and results of operations could be materially adversely affected by any of these risks. This report also contains forward- looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward- looking statements as a result of certain factors including the risks described below and elsewhere in this report and our other SEC filings. For a summary of the risk factors included in this Item 1A and for further details on our forward- looking statements, see “ Forward- Looking Statements and **Risk Factor** Summary of Risk Factors” on page 1. Risks related to our ability to successfully compete in the marketplace Sales of our generic medicines comprise a significant portion of our business, and we are subject to the significant risks associated with the generic pharmaceutical business. **Sales of our generics medicines have historically represented and are expected to continue to represent a significant portion of our business.** In 2022-2023, total revenues from sales of our generic medicines in all our business segments were \$ 8, 601-734 million, or ~~58-55~~ % of our total revenues. **As part of our Pivot to Growth strategy, we intend to focus on a prioritized portfolio and pipeline of high- value generic opportunities. However, Generic-generic** pharmaceuticals are, as a general matter, less profitable than innovative medicines, and have faced price erosion in each of our business segments, placing even greater importance on our ability to continually introduce new products. ~~We have become~~ **Although we intend to invest in the development of** more dependent on sales of our **complex, high- value** generics **products** medicines and are increasingly subject to market and regulatory factors and other risks affecting generic pharmaceuticals worldwide. In recent years, our business has experienced increased volatility in volumes due in large part to global supply chain issues and the COVID- 19 pandemic. In 2022, the global economy was continuing to recover from the impacts of the COVID- 19 pandemic and also began experiencing additional macroeconomic pressures such as rising inflation **drug device combinations** and **long-** disruptions to the global supply chain, in part resulting from the ongoing conflict between Russia and Ukraine. Due to the complexity of our supply chain, we have experienced supply discontinuities due to macroeconomic issues, regulatory actions- **acting injectables**, **there is no assurance as** including sanctions and trade restrictions, labor disturbances and approval delays, which impacted our ability to timely meet demand **when we will be successful** in **achieving** certain instances. These adverse market forces have a direct impact on our **expected** overall performance. Any such disruptions could have a material adverse impact on our business and our results, **if at all** of operation and financial condition. We also expect to continue to experience significant adverse challenges in the U. S. generics market deriving from limitations on our ability to influence generic medicine pricing in the long term and a decrease in value from future launches and growth. These and other challenges have required us to recognize significant goodwill impairments in past years. If we experience further difficulty in this market, this may continue to adversely affect our revenues and profits from our North America business segment or cause us to recognize one or more goodwill impairments relating to this reporting unit. Sales of our generic products may be adversely affected by the concentration of our customer base and commercial alliances among our customers. A significant portion of our sales are made to relatively few U. S. retail drug chains, wholesalers, managed care purchasing organizations, mail order distributors and hospitals. These customers have undergone significant consolidation and formed various commercial alliances, which may continue to increase the pricing pressures that we face in the United States. The presence of large buying groups, and the prevalence and influence of managed care organizations and similar institutions, have increased pressure on price, as well as terms and conditions required to do business. There are three large Group Purchasing Organizations (“ GPOs ”) that account for more than 80 % of generics purchases in the United States in 2022-2023, which provides each of them with significant bargaining power. **Additionally, our customers may form commercial alliances which result in heightened pricing pressure and competition in the markets in which we operate. For example, several major hospital systems in the United States formed a nonprofit company in 2018 to manufacture their own generics medicines.** We expect the trend of increased pricing pressures from our customers and price erosion in the U. S. generics market to continue. **Furthermore, the traditional model for distribution of pharmaceutical products is also undergoing disruption as a result of the entry or potential entry of new competitors and significant mergers among key industry participants, including Mylan and Pfizer’s Upjohn merger in November 2020, forming Viatrix Inc. In addition, several major hospital systems in the United States announced a plan to form a nonprofit company that will provide U. S. hospitals with a number of generic drugs. These and similar changes to the traditional supply chain could lead to our customers having increased negotiation leverage and to additional pricing pressure and price erosion.** Our net sales may also be affected by fluctuations in the buying patterns of our significant customers, whether resulting from seasonality, pricing, wholesaler buying decisions or other factors. In addition, since a significant portion of our U. S. revenues is derived from relatively few key customers, any financial difficulties experienced by a single key customer, ~~or~~ any delay in receiving payments from such a customer, **or any significant reduction in or loss of business with such a customer** could have a material adverse effect on our business, financial condition and results of operations. **For a description of our net sales from our major customers, see note 19 to our consolidated financial statements.** Our revenues and profits from generic products may decline as a result of competition from other pharmaceutical companies and changes in regulatory policy. Our generic drugs face intense competition. Prices of generic drugs may, and often do, decline, sometimes dramatically, especially as additional generic pharmaceutical companies receive approvals and enter the market for a given product and competition intensifies. Consequently, our ability to sustain our sales and profitability on any given product over time is affected by the number of

companies selling such product, including new market entrants, and the timing of their approvals. The goals established under the Generic Drug User Fee Act, and increased funding of the FDA's Office of Generic Drugs, have led to more and faster generic approvals, and consequently increased competition for some of our products. The FDA has stated that it has established new steps to enhance competition, promote access and lower drug prices and is approving **increasing record-breaking** numbers of generic applications. While these FDA improvements are expected to benefit our generic product pipeline, they will also benefit competitors that seek to launch products in established generic markets where we currently offer products. **In recent years and profitability can be substantially increased in the period following the introduction of such product and prior to a competitor's introduction of a generic product.** Even after the exclusivity period ends, there **has also been an increase** in often continuing benefit from having the first generic product in the market. However, the number of generic manufacturers targeting significant new generic opportunities with exclusivity under the Hatch- Waxman Act, or which are complex to develop, **has increased in recent years**. Additionally, many **Many** of the smaller generic manufacturers have increased their capabilities, level of sophistication and development resources in recent years. The FDA has also been limiting the availability of exclusivity periods for new products, which reduces the economic benefit from being first- to- file for generic approvals. **For example, the 180- day market exclusivity period under the Hatch- Waxman Act for a new product can be forfeited by failure to obtain approval or to launch a product within a specified time or if certain conditions exist, some of which may be outside our control.** The failure to maintain our industry- leading performance in the United States on first- to- file opportunities and to develop and commercialize high complexity generic products could adversely affect our sales and profitability. **The 180-** Furthermore, brand pharmaceutical companies continue to manage products in a challenging environment through marketing agreements with payers, pharmacy benefits managers and generic manufacturers. For example, brand companies often sell or license their own generic versions of their products, **known as "authorized generics,"** either directly or through other generic pharmaceutical companies (**so-called "authorized generics"**). No significant regulatory **28**-approvals are required for authorized generics, and brand companies do not face any other significant barriers to entry into such market. Brand companies may seek to delay introductions of generic equivalents through a variety of commercial and regulatory tactics. Many pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic (including biosimilar) competition. These efforts have included pursuing new patents for existing products to extend patent protection; **obtaining new regulatory exclusivities;** selling the brand product as their own **generic equivalent (an authorized generic generics)**; using the Citizen Petition process to request amendments to FDA standards or otherwise delay generic (or biosimilar) drug approvals; seeking changes to U. S. Pharmacopeia, an organization which publishes industry recognized compendia of drug standards; using the legislative and regulatory process to have drugs reclassified or rescheduled; attaching patent extension amendments to unrelated federal legislation; and entering into agreements with pharmacy benefit management companies to block the dispensing of generic (including biosimilar) products. These actions may increase the costs and risks of our efforts to introduce generic products and may delay or prevent such introduction altogether. In addition, the U. S. Congress and various state legislatures in the United States have passed, or have proposed passing, legislation that could have an adverse impact on pharmaceutical manufacturers' ability to (i) settle litigation initiated pursuant to the Hatch- Waxman Act and Biologics Price Competition and Innovation Act ("BPCIA"); (ii) secure the full benefit of first- to- file regulatory approval status secured under the Hatch- Waxman Act; and (iii) recover their investments into the development of an innovative, generic or biosimilar product. Hatch- Waxman and BPCIA create various pathways for generic drug manufacturers to secure accelerated approvals of their abbreviated new drug applications and abbreviated biologics license applications. The new laws and proposals from the federal and state governments could serve to change, directly and indirectly, the Hatch- Waxman Act and BPCIA, including the incentives to develop generic and biosimilar products, as well as the ability of generic manufacturers to accelerate the launch of their new generic and biosimilar products. They also could impact the ability of brand manufacturers to protect their investments in the **28** intellectual property associated with their branded specialty and innovative biologic products. Additionally, the enactment of the Inflation Reduction Act of 2022 (the "IRA") represents the most significant pharmaceutical pricing reform in the United States to date and includes legislative changes that could lead to greater pricing pressures on our products such as amendments to (i) eliminate the "donut hole" under the Medicare Part D program beginning in 2025; (ii) modify the "noninterference" provisions of the Medicare Part D enabling statute to require the U. S. Department of Health and Human Services ("HHS") to negotiate the prices of a subset of drugs and biologics with the highest annual expenditures under Medicare Parts B and D; and (iii) impose **manufacturer rebate rebates requirements on manufacturers of certain single- source drugs and biologics covered under Medicare Part B and any Part D covered, FDA- approved drug or biologic or biosimilar, as well as generic drugs** **when prices rise faster than the rate of inflation**. A number of state legislatures have also begun considering legislation that would implement IRA- like frameworks for state regulated insurance markets. We continue to monitor these legislative developments, **and** evaluate whether any changes to our business practices and operations are necessary in order to comply with such legislative reforms and advocate for policies that support both innovation and access to high quality medicines for patients. However, we cannot accurately predict the ultimate impact of such legislative developments on our business or whether additional changes in regulatory policies will occur in the future. We have experienced, and may continue to experience, delays in launches of our new generic products. Although we believe we have one of the most extensive pipelines of generic products in the industry, in recent years we were unable to successfully execute a number of generic launches and these challenges may continue in the foreseeable future. As a result of delays we have experienced in the timing of launches, we may not be able to realize the economic benefits anticipated in connection with our planned launch timing. If we cannot execute timely launches of new products, we may not be able to offset the increasing price erosion on existing products in the United States resulting from pricing pressures and accelerated generics approvals for competing products. Such unsuccessful launches can be caused by many factors, including, delays in regulatory approvals, lack of operational or clinical readiness or patent litigation. Failure or delays to execute launches of new generic products could have a material adverse effect

on our business, financial condition and results of operations. ²⁹ The increase in the number of..... are able to commercialize a product. We may be unable to take advantage of the increasing number of high- value biopharmaceutical biosimilars opportunities. We aim to be a global leader in biopharmaceuticals. We are developing a product **As part of our Pivot to Growth strategy, we intend to capitalize on our late- stage pipeline of and manufacturing capabilities for biosimilar products** , which are expected to make up an increasing proportion of the high- value generic opportunities in the coming years. The development, manufacture and commercialization of biopharmaceutical biosimilar products require specialized expertise and are very costly and subject to complex evolving regulation , which is still evolving. Due to the complex process and significant financial and other resources required to develop biosimilars, obstacles and delays, including budget constraints may arise, which increase the cost of development or force us to abandon a potential product in which we may have invested substantial amounts of time and resources. We **have made** were behind many of our competitors in developing biopharmaceuticals and **will continue to make** are making and still require significant investments and collaborations with third parties to benefit **capitalize on biosimilar opportunities. However, the market for biosimilar products, in particular for key lifecycle products, is facing increasingly intense competition, including from new market entrants, growing pricing pressures, as well as from existing innovative products that maintain a significant market share, and these there is no assurance that we will be able to successfully capitalize on biosimilar opportunities.** Failure to develop and commercialize biopharmaceuticals biosimilars , either by us or through collaborations with third parties, could have a material adverse effect on our business, financial condition, results of operations and prospects. Our innovative medicines face intense competition from companies that have greater resources and capabilities **and we must make significant investments in our pipeline of innovative medicines to address such competition, which may not achieve expected results** . We face intense competition to our innovative medicines. **As part of our Pivot to Growth strategy, we intend to deliver on our growth engines, mainly AUSTEDO, AJOVY and UZEDY, and step up the innovation of our late- stage innovative pipeline assets. However, Many-many** of our competitors are larger and / or have substantially more experience in the development, acquisition and marketing of branded, innovative and consumer- oriented ²⁹ products. They may be able to respond more quickly to new or emerging market preferences or to devote greater resources to the development and marketing of new products and / or technologies than we can. As a result, any products and / or innovations that we develop may become obsolete or noncompetitive before we can recover the expenses incurred in connection with their development. In addition, we must demonstrate the benefits of our products relative to competing products that are often more familiar or otherwise better ³⁰ established to physicians, patients and third-party payers. If competitors introduce new products or new variations on their existing products, our marketed products, even those protected by patents, may be replaced in the marketplace or we may be required to lower our prices. For example, the following may have a significant effect on our financial results and cash flow: • **Our-our** future success depends on our ability to maximize the growth and commercial success of AUSTEDO **and AUSTEDO XR** . If our revenues derived from AUSTEDO **and AUSTEDO XR** do not increase as expected or if we lose market share to competing therapies, it may have an adverse effect on our results of operations -; • AJOVY faces strong competition from two products that were introduced into the market around the same time and are competing for market share in the same space, as well as from other emerging competing therapies, including oral calcitonin gene **CGRP products; • UZEDY is a later entrant which faces competition from four well - established related peptide (“ CGRP”)-products. Additionally, two branded and one generic risperidone long- acting injectable have or are in the process of launching, which may impact UZEDY’ s growth; • COPAXONE faces increasing competition from generic versions in the U. S. and competing glatiramer acetate products in Europe, as well as from orally-administered therapies. Following the approval of generic competition, COPAXONE’ s revenues and profitability have decreased. We expect the trend of decreasing revenues and profitability for COPAXONE to continue in the future ; and • there is a trend in the innovative medicines industry of seeking to “ outsource ” drug development by acquiring companies with promising drug candidates and we face substantial competition from historically innovative companies, as well as companies with greater financial resources than us, for such acquisition targets. In order to remain competitive, we must invest significant resources to expand our pipeline for innovative medicines and biosimilars, both through our own efforts and through collaborations with, and in- licensing or acquisition of products from, third parties. We have entered into, and expect to pursue, in- licensing, acquisition, collaboration, funding and partnership opportunities to supplement and expand our existing innovative medicines and biosimilar pipeline, such as our collaborations with Alvotech, Modag, Sanofi, Royalty Pharma and Biologic. However, there is no assurance that such collaborations will achieve the results we expect and we or our counterparties could fail to perform the obligations thereunder, including due to the failure to obtain regulatory approvals and increasing competition, pricing pressures and other financial constraints. Furthermore, the development of innovative medicines involves lengthier and more complex processes and greater expertise and resources than those used in the development of generic medicines. For example, the time from discovery to commercial launch of an innovative medicine can be 15 years or more and involves multiple stages, including intensive preclinical and clinical testing and highly complex, lengthy and expensive regulatory approval processes, which vary from country to country. The longer it takes to develop a new product, the less time that remains to recover development costs and generate profits. During each stage, we may encounter obstacles that delay the development process and increase expenses, potentially forcing us to abandon a potential product in which we may have invested substantial amounts of time and resources. These obstacles may include preclinical failures, difficulty enrolling patients in clinical trials, delays in completing formulation and other work needed to support an application for approval, adverse reactions or other safety concerns arising during clinical testing, insufficient clinical trial data to support the safety or efficacy of the product candidate, widespread supply chain breakdowns, delays as a result of new requirements implemented by health authorities such as the U. S. FDA and EMA requirement on material use, and delays or failures to obtain required regulatory ³⁰ approvals for the product candidate or the facilities in which it is manufactured . In addition, our innovative**

medicines require much greater use of a direct sales force than does our core-generics business. Our ability to realize significant revenues from direct marketing and sales activities depends on our ability to attract and retain qualified sales personnel. Competition for qualified sales personnel is intense. We may also need to enter into co-promotion, contract sales force or other such arrangements with third parties, for example, where our own direct sales force is not large enough or sufficiently well-aligned to achieve maximum market penetration. Any failure to attract or retain qualified sales personnel or to enter into third-party arrangements on favorable terms could prevent us from successfully maintaining current sales levels or commercializing new innovative medicines. If generic or biosimilar products that compete with any of our innovative medicines are approved and sold, sales of our innovative medicines will be adversely affected. Certain of our leading innovative medicines face patent challenges and impending patent expirations. For example, following our own launch of a ProAir authorized generic in the U. S. in January 2019, the launch of an **and** additional generic version of Ventolin® HFA and other generic versions of ProAir in 2020, we discontinued marketing ProAir HFA in October 2022, while focusing our marketing efforts on albuterol sulfate inhalation aerosol (our ProAir authorized generic) and ProAir Digihaler (albuterol sulfate 117 mcg). Some **some** of our other innovative medicines have recently become susceptible to generic competition, such as TREANDA in 2022, and we reached agreements with Lupin and Aurobindo to resolve the disputes in connection with their ANDAs filed for generic deutetrabenazine (AUSTEDO). Generic equivalents and biosimilars for branded pharmaceutical products are typically sold at lower costs than the branded products. After the introduction of a competing generic product, a significant percentage of the prescriptions previously written for the branded product are often written for the generic version. Legislation enacted in most U. S. states allows or, in some instances, mandates that a pharmacist dispense an available generic equivalent (or interchangeable biosimilar) when filling a prescription for a branded product in the absence of specific instructions from the prescribing physician. Branded products typically experience a significant loss in revenues following the introduction of a competing generic (or biosimilar) product, even if the branded product is still subject to an existing patent since generic manufacturers may offer generic (or biosimilar) products while patent litigation is pending. Our innovative medicines are or may become subject to competition from generic equivalents because our patent protection expired or may expire soon. In addition, we may not be successful in our efforts to obtain additional patent protection for our innovative medicines through the development and commercialization of proprietary product improvements and new and enhanced dosage forms. **31** Investments in our pipeline of innovative medicines and other products may not achieve expected results. We must invest significant resources to develop innovative medicines and biosimilars, both through our own efforts and through collaborations with, and in-licensing or acquisition of products from, third parties. We have entered into, and expect to pursue, in-licensing, acquisition and partnership opportunities to supplement and expand our existing innovative medicines and biosimilar pipeline (e. g., the transactions with Alvotech and Modag). The development of innovative medicines involves processes and expertise different from those used in the development of generic medicines, which increase the risk of failure. For example, the time from discovery to commercial launch of an innovative medicine can be 15 years or more and involves multiple stages, including intensive preclinical and clinical testing and highly complex, lengthy and expensive approval processes, which vary from country to country. The longer it takes to develop a new product, the less time that remains to recover development costs and generate profits. During each stage, we may encounter obstacles that delay the development process and increase expenses, potentially forcing us to abandon a potential product in which we may have invested substantial amounts of time and resources. These obstacles may include preclinical failures, difficulty enrolling patients in clinical trials, delays in completing formulation and other work needed to support an application for approval, adverse reactions or other safety concerns arising during clinical testing, insufficient clinical trial data to support the safety or efficacy of the product candidate, widespread supply chain breakdowns, delays as a result of new requirements implemented by health authorities such as the U. S. FDA and EMA requirement on material use, and delays or failure to obtain the required regulatory approvals for the product candidate or the facilities in which it is manufactured. When we enter into partnerships, joint ventures or strategic alliances with third parties, such as our collaborations with Alvotech and Modag, we face the risk that some of these third parties may fail to perform their obligations, which in certain circumstances include obtaining regulatory approvals, or fail to reach the levels of success that we are relying on to meet our revenue and profit goals. There is a trend in the innovative medicines industry of seeking to “outsource” drug development by acquiring companies with promising drug candidates and we face substantial competition from historically innovative companies, as well as companies with greater financial resources than us, for such acquisition targets. Our success depends on our ability to develop and commercialize additional pharmaceutical products. Our financial results depend upon our ability to develop and commercialize additional **innovative, biosimilar and** generic, **innovative and biosimilar** products in a timely manner, **particularly in light of the generic competition to our existing innovative medicines**. Commercialization requires that we successfully develop, test and manufacture pharmaceutical products. All of our products must receive regulatory approval and meet **(, and continue to comply with),** regulatory and safety standards; if health or safety concerns arise with respect to a product, we may be forced to withdraw it from the market. Developing and commercializing additional pharmaceutical products is also subject to difficulties relating to the availability, on commercially reasonable terms, of raw materials, including API and other key ingredients; preclusion from commercialization by the proprietary rights of others; the costs of manufacture and commercialization; costly legal actions brought by our competitors that may delay or prevent development or commercialization of a new product; and delays and costs associated with the approval process of the FDA and other U. S. and international regulatory agencies. The development and commercialization process, particularly with respect to innovative medicines and biosimilar medicines, as well as **the** complex generic medicines that we increasingly focus on, is both time-consuming and costly, and involves a high degree of business risk. Our products currently under development, if and when fully developed and tested, may not perform as we expect. Necessary regulatory approvals may not be **32** obtained in a timely manner, if at all, and we may not be able to produce and market such products successfully and profitably. Delays in any part of the process or our inability to obtain regulatory approval of our products could adversely affect our operating results by restricting or delaying our

introduction of new products. We depend on the effectiveness of our patents, confidentiality agreements and other measures to protect our intellectual property rights. The success of our innovative medicines business depends substantially on our ability to obtain patents and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products identical or similar to ours. We have been issued numerous patents **31** covering our innovative medicines, and have filed, and expect to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the United States. Currently pending patent applications may not result in issued patents or be approved on a timely basis or at all. Any existing or future patents issued to or licensed by us may not provide us with any competitive advantages for our products or may be challenged or circumvented by competitors or governments. Efforts to defend the validity of our patents are expensive and time-consuming, and there can be no assurance that such efforts will be successful. Our ability to enforce our patents also depends on the laws of individual countries and each country's practices regarding the enforcement of intellectual property rights. The loss of patent protection or regulatory exclusivity on innovative medicines, **including potential challenges to our Orange Book patent listings in the United States**, could materially impact our business, results of operations, financial condition and prospects. We also rely on trade secrets, unpatented proprietary know-how, trademarks, regulatory exclusivity and continuing technological innovation that we seek to protect, in part by confidentiality agreements with licensees, suppliers, employees and consultants. These measures may not provide adequate protection for our unpatented technology. If these agreements are breached, it is possible that we will not have adequate remedies. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors or we may not be able to maintain the confidentiality of information relating to such products. If we are unable to adequately protect our technology, trade secrets or proprietary know-how, or enforce our intellectual property rights, our results of operations, financial condition and cash flows could suffer. Risks related to our substantial indebtedness. We have substantial debt **outstanding** of \$ 21, 212 million as of December 31, 2022, which requires significant interest and principal payments, requires compliance with certain covenants and restricts our ability to incur additional indebtedness or engage in other transactions. **Our As of December 31, 2023, we have consolidated debt was of \$ 19, 833 million outstanding, compared to \$ 21, 212 million at outstanding as of December 31, 2022, compared to \$ 23, 043 million at December 31, 2021.** If we are unable to meet our debt service obligations and other financial obligations, we could be forced to restructure or refinance our indebtedness and other financial transactions, seek additional debt or equity capital or sell our assets. We **may** might then be unable to obtain such financing or capital or sell our assets on satisfactory terms, if at all. Any refinancing of our indebtedness could be at significantly higher interest rates, incur significant transaction fees or include more restrictive covenants. See "Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity" and note 9 to our consolidated financial statements for a detailed discussion of our outstanding indebtedness. ~~We may have lower than anticipated cash flows in the future, which could further reduce our available cash. Although we believe that we will have access to cash sufficient to meet our business objectives and capital needs, this reduced availability of cash could constrain our ability to grow our business.~~ Our unsecured syndicated sustainability-linked revolving credit facility ("RCF") contains certain covenants, including certain limitations on incurring liens and indebtedness and maintenance of certain financial ratios, including a maximum leverage ratio, which becomes more restrictive over time. Under specified circumstances, including non-compliance with any of the covenants and the unavailability of any waiver, amendment or other modification thereto, we will not be able **33** to borrow under the RCF. Additionally, violations of the covenants, under certain circumstances, would result in an event of default in all borrowings under the RCF and, when greater than a specified threshold amount as set forth in each series of senior notes and sustainability-linked senior notes is outstanding, could lead to an event of default under our senior notes and sustainability-linked senior notes due to cross acceleration provisions. **While As of December 31, 2022, we were in compliance with all applicable financial ratios. We continue to take steps to reduce our debt levels and improve profitability, if we fail to satisfy our ensure continual compliance with the financial maintenance ratio covenants. If such covenants will not be met, we may need believe we will be able to renegotiate and amend the covenants, or refinance the debt with different repayment terms to address such situation as circumstances warrant. We Although we have successfully negotiated amendments to our loan agreements in the past, we cannot guarantee that we will be able to amend such agreements or refinance such debt on terms satisfactory to us, or at all, if required to maintain compliance in the future.** If we experience lower than **required anticipated** earnings and/or cash flows, **to continue to maintain compliance and efforts with our financial ratio covenants, we may curtail spending or divest assets, which could constrain** not be successfully completed on commercially acceptable terms, we may curtail additional planned spending, may divest additional assets in order to generate enough cash to meet our **ability to grow our business** debt requirements and all other financial obligations. **32** Our substantial net debt could also have other important consequences to our business, including, but not limited to: ~~making it more difficult for us to satisfy our obligations; limiting our ability to borrow additional funds and increasing the cost of any such borrowing; increasing our vulnerability to, and reducing our flexibility to respond to, general adverse economic and industry conditions; limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; placing us at a competitive disadvantage as compared to our competitors, to the extent that they are not as highly leveraged; and restricting us from pursuing certain business opportunities.~~ Additionally, ~~if macroeconomic pressures continue to impact our business and financial results for an extended period of time,~~ our credit losses, liquidity and cash resources could be negatively impacted **by macroeconomic pressures**. We may be required to draw down funds from our RCF or pursue additional sources of financing to fund our operations, such as secured financing. If we seek secured financing in excess of the ~~limitation~~ **limitations** in our **existing** debt instruments, we may have to secure our ~~current~~ outstanding debt as well. Capital and credit markets, which have been disrupted by such macroeconomic pressures, have experienced ~~increased~~ volatility. As a result, access to additional financing may be challenging and is largely dependent upon ~~evolving~~ market conditions and other factors,

which could materially impact our business, results of operations, financial condition and prospects. We may need to raise additional funds in the future, which may not be available on acceptable terms or at all. We may consider issuing additional debt or equity securities in the future to refinance existing debt or for general corporate purposes, including to fund **our growth strategies, and to fund** potential acquisitions or investments. If we issue ordinary equity, convertible preferred equity or convertible debt securities to raise additional funds, our existing shareholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing shareholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest and potentially lowering our credit ratings. We may not be able to market such issuances on favorable terms, or at all, in which case, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements. ³⁴If our credit ratings are further downgraded by leading rating agencies, we may not be able to raise debt or borrow funds in amounts or on terms that are favorable to us, if at all. Our credit ratings impact the cost and availability of future borrowings and, accordingly, our cost of capital. Our ratings at any time will reflect each rating agency's then-opinion of our financial strength, operating performance and ability to meet our debt obligations. In the past, we have been subject to downgrades in our credit ratings by various ratings agencies. Most recently, Standard and Poor's Financial Services LLC ("**S & P Standard and Poor's**") downgraded our rating from BB to BB- due to rising litigation risks. Subsequently, on July 29, 2022, following our announcement of reaching an agreement in principle on the financial terms of a nationwide settlement of the opioids litigation, **S & P Standard and Poor's** revised our rating outlook to positive, ~~reflecting our continued solid competitive position and robust free cash flow generation~~. However, there is no assurance that we will not be subject to ratings downgrades or negative outlooks by any of the ratings agencies in the future. **If our results of operations experience any negative trends or otherwise fail to meet analyst or investor expectations, we may experience ratings downgrades or negative outlooks by ratings agencies and our share price and reputation may be negatively impacted.** Any downgrade of our ratings by the rating agencies limits our ability to borrow at interest rates consistent with the interest rates that were available to us prior to such downgrades. This may limit our ability to sell additional debt securities or borrow money in the amounts, at the times or interest rates, or upon the terms and conditions that would have been available to us if our previous credit ratings had been maintained. ~~Additional~~ **risks** ~~Risks~~ related to our **general** business and operations Global economic conditions may negatively affect us and may magnify certain risks that affect our business. In ~~recent months, record levels of inflation have resulted in significant volatility and disruptions in the global economy.~~ In response to rising inflation **in recent years**, central banks in the markets in which we operate, including the United States Federal Reserve, have tightened their monetary policies and raised interest rates, and such measures may continue ~~if there is a period of sustained heightened inflation~~. Higher interest rates and volatility in financial markets could lead to additional economic uncertainty or recession. Increased inflation rates have increased our and our suppliers' operating costs, including labor costs, raw materials costs, manufacturing costs, ~~freight costs~~ and R & D costs. There is no assurance that we will be able to ~~promptly~~ increase our pricing to offset our increased costs, or that our operations will not be materially impacted by rising inflation and its broader effects on the markets in which we operate in the future. In addition to rising inflation, the global economy has also been impacted by fluctuating foreign exchange rates and geopolitical tensions, ~~such as the ongoing conflict between Russia and Ukraine, which could result in~~ ~~has spurred rising energy costs and exacerbated disruptions to the global supply chain~~ **disruptions** ~~caused by the COVID-19 pandemic and the government and societal responses to the pandemic~~. Supply chain disruptions could continue to result in delays in our production and distribution processes, R & D initiatives and our ability to timely respond to consumer demand. As we have substantial international operations, fluctuations in exchange rates between the currencies in which we operate ~~and the U. S. dollar~~ could increase our operating costs and adversely affect our results of operations, profits and cash flows. **The duration** ~~We have implemented certain measures in response to such macroeconomic pressures, including maintaining multiple supply sources for certain of our raw materials and~~ **extent** ~~employing various derivative financial instruments and hedging strategies to manage our exposure to exchange rate risks, which measures may mitigate, but do not eliminate, such economic pressures and their impact on us. We are continuing to monitor the effects of rising inflation~~ **, higher interest rates**, foreign exchange rate fluctuations, geopolitical tensions and other macroeconomic headwinds ~~on our business performance and financial condition. However, the duration and extent of such macroeconomic developments are uncertain and we cannot accurately predict whether we will be able to effectively and timely mitigate their impact on our business~~. **Due to the complexity of our supply chain, we have experienced supply discontinuities due to macroeconomic issues, regulatory actions, including sanctions and trade restrictions, labor disturbances and approval delays, which impacted our ability to timely meet demand in certain instances. These adverse market forces have a direct impact on our overall performance. Any such disruptions could have a material adverse impact on our business and our results of operation and financial condition.** The widespread outbreak of an illness or any other communicable disease, or any other public health crisis, ~~such as~~ ~~and the governmental and societal responses thereto, could adversely affect our business, results of operations and financial condition. Widespread outbreaks of disease or other public health crises and responses thereto have in the past and may in the future negatively impact the global economy, disrupt global supply chains and create significant volatility and disruption of financial markets. For example, during~~ the COVID-19 pandemic ~~and the governmental and societal responses thereto, we experienced~~ could adversely affect our business, results of operations and financial condition. Widespread outbreaks of disease or other public health crises, such as the COVID-19 pandemic ~~and responses thereto have in the past and may in the future negatively impact the global economy, disrupt global~~ ³⁵supply chains and create significant volatility and disruption ~~disruptions~~ of financial markets. Since it began in 2019, the COVID-19 pandemic has spread globally, including to countries and regions where **in which** we manufacture ~~most of our products and conduct our clinical trials~~, **as well as changes in customer stocking and purchasing patterns**. In response to the COVID-19 pandemic, we temporarily closed certain of our facilities and faced other protectionist measures and restrictions

imposed by government authorities to control the pandemic which inhibited our employees' access to our facilities, and caused certain delays and disruptions in our materials, supply. **The** More recently, the disruption from the COVID- 19 pandemic **also resulted** has decreased and in 2022, we did not experience material delays in **our** the production and distribution of medicines caused by the COVID- 19 pandemic. However, we experienced delays in some clinical trials in 2022 due to slowdowns in recruitment for studies and suspended regulatory inspections, delays in regulatory approvals of new products due to reduced capacity or re- prioritization of regulatory agencies and delays in pre- commercial launch activities. **Additionally, the COVID- 19 pandemic continued to have an impact to a certain extent on markets and on customer stocking and purchasing patterns.** The new working environment that **has** emerged as a result of the COVID- 19 pandemic, with many employees working remotely, **has** also increased the exposure of many companies, including us, to cyber- attacks and data security breaches. **Future outbreaks of disease** If such breach were to occur, it may **including a resurgence of COVID- 19, could similarly** have a material adverse effect **impact** on **the global economy, our supply chain and** our business operations and reputation. **We In response to the COVID- 19 pandemic, we** have taken precautionary measures, and may take additional measures, intended to minimize the risks of the COVID- 19 pandemic **future potential public health crises** to our employees and operations. **However** While we expect to be able to continue our operations and to satisfy the demand for our products, while protecting the health and safety of our employees and customers, the uncertainty surrounding the full economic implications of the pandemic may result in business disruption and it is **not** possible that we will continue to see variable demand in **predict the impact of** future outbreaks periods. Though availability of **disease** vaccines and reopening of economies has improved the outlook for **or** recovery from the COVID- 19 pandemic's impacts, the impact of other **the government** new, more contagious or lethal variants that may emerge, the effectiveness of COVID- 19 vaccines against such variants or the related responses **thereto** by governments, including reinstated government- imposed lockdowns or other measures, cannot be predicted at this time. Any disruptions caused by the COVID- 19 pandemic, or any new outbreaks of disease that may emerge in the future, could have a material adverse impact on our operational and financial performance, including our ability to execute our business strategies in the expected time frame or at all. **34** Implementation of ongoing optimization efforts may adversely affect our business, financial condition and results of operations. We **have and will continue to implement changes to optimize our business operations and reallocate resources towards growth opportunities. As part of such optimization efforts, we** may face wrongful termination, discrimination or other legal claims from employees affected by ongoing changes in our workforce. We may incur substantial costs defending against such claims, regardless of their merits, and such claims may significantly increase our severance costs. **Additionally, we may see variances in the estimated severance costs depending on the category of employees and locations in which severance is incurred.** Upon the proposed divestiture of any **assets, including divestitures of business units as part of our Pivot to Growth strategy to focus on our core businesses, as well as divestitures of our facility facilities** in connection with our ongoing plant optimization, we may not be able to **divest consummate** such **facility divestitures** at a favorable price or in a timely manner. Any divestiture that we are unable to complete may cause additional costs associated with retaining **the facility or** closing **and or** disposing of the impacted businesses. Any workforce reduction and site consolidation may result in the loss of numerous long- term employees, the loss of institutional knowledge and expertise, the reallocation of certain job responsibilities and the disruption of business continuity, all of which could negatively affect operational efficiencies and our ability to achieve growth and profitability through the development and sale of new pharmaceutical products. We cannot guarantee that, following such efficiency measures, our business will be more efficient or effective. Our continued success depends on our ability to attract, hire, integrate and retain highly skilled key personnel. Given the size, complexity and global reach of our business and our multiple areas of focus, we are especially reliant upon our ability to recruit and retain highly qualified management and other key employees. **36** Our ability to attract and retain such employees may be diminished by the financial, legal and regulatory challenges we have faced in recent years, the increased importance of delivering on corporate ESG goals and their reputational impact as well as increased competition for talent. In addition, the success of our R & D activity depends on our ability to attract and retain sufficient numbers of skilled scientific personnel, which may be limited due to our R & D spending and programs. Changes in our management as a result of the appointment or departure of members of management and other key employees, **such as the recent appointment of our new President and Chief Executive Officer,** may also cause disruptions to our business and result in the loss of key personnel with institutional knowledge of our business, negative impacts on our relationships with existing employees and customers and increased operating costs related to integrating new personnel. Any difficulty in recruiting, hiring, integrating, retaining and motivating talented and skilled members of our organization may **impair or** delay **or prevent the achievement of major business.....** **regulatory actions have and may adversely impact** our ability to **execute** supply various products around the world and to obtain approvals for new products manufactured at the affected facilities. If any regulatory body were to require one or **our Pivot** more of our significant manufacturing facilities to **Growth strategy** cease or limit production, or to halt the approval of new or pending regulatory applications, our business and reputation could be adversely affected. In addition, because regulatory approval to manufacture a drug is site- specific, the delay and cost of remedial actions or obtaining approval to manufacture at a specific facility could have a material adverse effect on our business, financial condition and results of operations. The manufacture of our products is highly complex, and an interruption in our supply chain or problems with internal or third party **manufacturing** information technology systems could adversely affect our results of operations. Our products are either manufactured at our own facilities or obtained through supply agreements with third parties. Many of our products are the result of complex manufacturing processes, and some require highly **37** specialized raw materials. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with or shortages of raw materials, natural disasters, and environmental factors. For some of our key raw materials, we have only a single, source of supply, and alternate sources of supply may not be readily available. If our supply of certain raw materials or finished products is interrupted from time to time, or proves insufficient to meet demand, our cash flows and results

of operations could be adversely impacted. Additionally, any such supply interruption could result in a supply shortage to patients depending on the number of competitors able to meet the supply needs. Moreover, the streamlining of our manufacturing network may result in our product supply becoming more dependent on a smaller number of specific manufacturing plants. Our inability to timely manufacture any of our key products may result in claims and penalties from customers and could have a material adverse effect on our business, financial condition and results of operations as well as result in reputational harm. **35** In recent years, medicine shortages have become an increasingly widespread problem around the world. We are working diligently across our supply chain to ensure continuous and stable supply. Many European countries are implementing legal and regulatory measures, such as mandatory stockpiling and high penalties in order to prevent supply disruptions. Such measures may lead to substantial monetary losses in case we experience long- term supply disruptions in the relevant territories. We also rely on complex shipping arrangements to and from the various facilities of our supply chain. Customs clearance and shipping by land, air or sea routes rely on and may be affected by factors that are not in our full control or are hard to predict. A significant portion of our costs is comprised of raw materials for our products as well as energy, transportation and labor costs for our manufacturing and operations. We have experienced increases in prices of raw materials, ~~energy, labor and transportation, in part due to macroeconomic pressures , including as a result of geopolitical tensions and conflicts such as the ongoing conflict between Russia and Ukraine.~~ While we seek to pass along such increased costs to our customers, there is no assurance that we will be able to successfully and promptly increase our pricing to offset such increased costs in the future. Our ability to increase our pricing may be limited or delayed by regulatory restrictions and we may only be able to increase our pricing to the extent our competitors also increase their prices, as any increase in our pricing exceeding that of our competitors could negatively impact our competitive position. Any failure to effectively and timely pass along our increased costs to our customers may adversely impact our results of operations and financial condition. Significant disruptions of our information technology systems could adversely affect our business. We rely extensively on information technology systems in order to conduct business, including ~~some systems that are~~ managed by third- party service providers. These systems include ~~, but are not limited to,~~ programs and processes relating to internal and external communications, ordering and managing materials from suppliers, converting materials to finished products, shipping products to customers, processing transactions, summarizing and reporting results of operations, **processing payments to employees and vendors, calculating sales receivables, generating our financial results,** and complying with **information technology security compliance and other** regulatory, legal or tax requirements. These information technology systems could be damaged or cease to function properly due to the poor performance or failure of third- party service providers, catastrophic events, power outages, network outages, failed upgrades or other similar events. If our business continuity plans do not effectively resolve such issues on a timely basis, we may suffer significant interruptions in conducting our business, which may adversely impact our business, financial condition and results of operations. Furthermore, our systems and networks have been, and are expected to continue to be, the target of ~~increasing~~ **increasingly** advanced ~~and evolving~~ **and evolving** cyber- attacks which may pose a risk to the security of our systems and the confidentiality, availability and integrity of our data, as well as disrupt our operations or damage our facilities or those of third parties. ~~As Our exposure to~~ **As Our exposure to** cybersecurity ~~risks may be heightened by~~ **risks may be heightened by** threats rapidly evolve in sophistication and become more prevalent, we are continually increasing our attention to these threats. We assess potential threats and vulnerabilities and make investments seeking to address them- ~~the global scope~~ **the global scope**, including ongoing monitoring and updating of networks and systems, increasing ~~38~~ **38** specialized information security skills, deploying employee security training and updating our ~~operations~~ **operations** security policies. However, because ~~Because~~ **Because** the techniques, tools and tactics used in cyber- attacks frequently change and may be difficult to detect for periods of time, ~~despite our attention to such threats and especially with the~~ **despite our attention to such threats and especially with the** ~~increasing use of artificial intelligence technology,~~ **increasing use of artificial intelligence technology,** we may face difficulties in anticipating and implementing adequate preventative measures or ~~fully~~ **fully** mitigating harms after such an attack. In addition, hardware, software or applications we develop or procure from third parties may contain defects in design or manufacture or other problems that could unexpectedly compromise information security. We outsource administration of certain functions to vendors that could be targets of cyber- attacks. Any ~~manipulation,~~ **manipulation,** theft, loss and / or fraudulent use of customer, employee or proprietary data as a result of a cyber- attack targeting us or one of our third- party service providers could subject us to significant litigation, liability and costs, as well as adversely impact our reputation with customers and regulators ~~, among others.~~ A cyber- attack on our information technology systems may lead to substantial interruptions in our business, legal claims and liability, regulatory investigations and penalties, and reputational damage, which could have a material adverse effect on our business, financial condition and results of operations. While we maintain insurance coverage that is designed to address certain aspects of cyber risks, such insurance coverage may be insufficient to cover all losses or all types of claims that may arise in the event we experience a cybersecurity incident, data security breach or disruption, unauthorized access or failure of systems. **36** A data security breach could adversely affect our business and reputation. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, proprietary business information and personally identifiable information (including of our employees, customers, suppliers and business partners). Any data breach may subject us to civil fines and penalties, or regulatory fines or sanctions such as under the GDPR, or equivalent under relevant national laws, the federal Health Insurance Portability and Accountability Act of 1996 (“ HIPAA ”) as amended, and other relevant state and federal privacy laws in the United States including the California Consumer Privacy Act (“ CCPA ”) and other laws and regulations including across our International Markets. ~~Additionally, we expect that new privacy and cybersecurity laws and regulations will be proposed and adopted in the U. S. and other jurisdictions in which we operate.~~ Our failure, or the failure of our third- party vendors, to comply with applicable laws and regulations ~~relating to data security~~ **relating to data security** and our involvement or the involvement of any of our third- party vendors in any ~~data cybersecurity~~ **data cybersecurity** ~~security~~ **security** incidents could result in legal claims and liability, obligations to report incidents to governmental agencies, regulatory investigations and penalties, and reputational damage, which could have a material adverse effect on our business, financial condition and results of operations. We have procedures, **tools, processes and services** in place

to detect and respond to cyber- attacks, data breaches, security incidents, and compromises of personal information. If our efforts to protect the security of data are unsuccessful, a cyber- attack, data breach, security incident, or compromise of personal information may result in costly legal claims and liability, financial penalties, government enforcement actions, for example under the GDPR, private litigation, negative publicity or a reduction in supply of essential medicines to the public, each of which could further result in reputation or brand damage with customers, and our business, financial condition, results of operations or prospects could suffer. ~~Because our facilities are located throughout the world, we are subject to varying intellectual property laws that may adversely affect our ability to manufacture our products. We are subject to intellectual property laws in all countries where we have manufacturing facilities. Modifications of such laws or court decisions regarding such laws may adversely affect us and may impact our ability to produce and export products manufactured in any such country in a timely fashion. Additionally, the existence of third- party patents in such countries, with the attendant risk of litigation, may cause us to move production to a different country (potentially leading to significant production delays) or otherwise adversely affect our ability to export certain products from such countries.~~ 39 We have significant operations globally, including in countries that may be adversely affected by political or economic instability, major hostilities or acts of terrorism, which exposes us to risks and challenges associated with conducting business internationally. We are a global pharmaceutical company with worldwide operations. ~~Although~~ **All but a majority- minor portion** of our sales in **2022-2023** were in **North America** the United States and ~~Western~~ Europe, **and** an increasing portion of our sales and operational network are located in other regions. **Certain of the regions in**, such as Latin America, Central and Eastern Europe and Asia, which **we operate** may be more susceptible to political and economic instability, such as **the state of war declared in Israel in October 2023 and the military activity in the region, and** the ongoing conflict between Russia and Ukraine, that could result in a loss of sales in such regions. ~~We~~ **Our global headquarters and several manufacturing and R & D facilities are located in Israel and currently remain largely unaffected, and we** have no manufacturing or R & D facilities in Russia or Ukraine. However, the duration, severity and global implications (including potential inflation and devaluation consequences) of ~~the these~~ **current conflict between Russia and Ukraine, rising tensions in Asia and the Middle East** and other geopolitical conflicts that may arise in the future, cannot be predicted at this time and could have an effect on our business, ~~including on our~~ exchange rate exposure, supply chain, operational costs and commercial presence in these markets. ~~Other countries and regions, such as the United States and Western Europe, also face potential instability due to political and other developments. In addition, in the United States, the executive administration has discussed, and in some cases implemented, changes with respect to certain trade policies, tariffs and other government regulations affecting trade between the United States and other countries.~~ As a company that manufactures most of its products outside the United States, a “ border adjustment tax ” or other restriction on trade, if enacted **by the United States**, may have a material adverse effect on our business, financial condition and results of operations. In addition, given that a significant portion of our business is conducted in the European Union and the U. K., the **departure of formal change in the relationship between the U. K. and from** the European Union (~~caused by the U. K. referendum to leave the European Union, referred to as “ Brexit ”~~), may pose certain implications to our research, commercial and general business operations in the U. K. and the European Union, including the approval and supply of our products. ~~On~~ **The Trade and Cooperation Agreement from** December 24, 2020, **between** the United Kingdom- U. K. and **the** European Union ~~agreed on a new Trade and Cooperation Agreement and on December 31, 2020, the United Kingdom formally left the European Union. The Trade and Cooperation Agreement~~ is comprehensive, but does not cover all areas of regulation pertinent to the pharmaceutical industry, so certain complexities remain. ~~This, and the~~ finalization of the long- term relationship ~~between the United Kingdom and the European Union~~ will dictate how both jurisdictions will be impacted and may result in an impact on our business operations in Europe. Significant portions of our operations are conducted outside the markets in which our products are sold, and accordingly we often import a substantial number of products into such markets. We may, therefore, be denied access to our customers or suppliers or denied the ability to ship products from any of our sites as a result of a closing of the borders of the countries in which we sell our products, or in which our operations are located, due to economic, legislative, political and military conditions, including hostilities and acts of terror, in such **37** countries. In addition, certain countries have put regulations in place requiring local manufacturing of goods, while foreign- made products are subject to pricing penalties or even bans from participation in public procurement auctions. We face additional risks inherent in conducting business internationally, including compliance with laws and regulations of many jurisdictions that apply to our international operations. These laws and regulations include **intellectual property laws,** data privacy requirements, labor relations laws, tax laws, competition regulations, import and trade restrictions, economic sanctions, export requirements, the Foreign Corrupt Practices Act (“ FCPA ”), the UK Bribery Act 2010 and other similar local laws that prohibit corrupt payments to governmental officials or certain payments or remunerations and provisions of things of value to customers and, in some cases, other private sector counterparties. **Modifications of such laws or court decisions regarding such laws may adversely affect us and may impact our ability to continue our international operations.** Given the high level of complexity of these laws, there is a risk that some provisions may be breached by us, for example through fraudulent or negligent behavior of individual employees (or third parties acting on our behalf), our failure to comply with certain formal documentation requirements, or otherwise. Actions by our employees, or by third- party intermediaries acting on our behalf, in violation of such laws, whether carried out in the United States or elsewhere in connection with the conduct of our business have exposed us, and may further expose us, to significant liability for violations of the FCPA or other anti- corruption laws. In 2016, we paid a monetary fine for FCPA violations and entered into a three- ~~year~~ deferred prosecution **40**-agreement with the DOJ, which included retaining an independent compliance monitor. The FCPA also requires us to keep and maintain accurate books and records and systems of internal controls to prevent bribery and corruption. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, implementation of compliance programs and prohibitions on the conduct of our business. Any such violation could include prohibitions on our ability to offer our products in one or more countries and could

materially damage our reputation, our brand, our ability to attract and retain employees, our business, our financial condition and our results of operations. Our corporate headquarters and a ~~sizable~~ portion of our manufacturing activities are located in Israel. Our Israeli operations are dependent upon materials imported from outside Israel. Accordingly, our operations and information technology systems could be materially and adversely affected by acts of terrorism, including through cybersecurity threats, or if major hostilities were to occur in the Middle East or trade between Israel and its present trading partners were materially impaired, including as a result of acts of terrorism in the United States or elsewhere. **The state of Israel declared war on October 7, 2023, and the military activity in the region, may result in disruption to our operations and facilities, loss of business with one or more such as customers, or our manufacturing and R & D facilities located in Israel, and impact our employees more such customers were to experience difficulty in paying us on a timely basis, some of our business, financial condition and results of which are military reservists being called operations could be materially adversely affected.** For a description of our revenue from our main customers, see note 19 to our consolidated financial statements. **active military duty, and impact the economic, social and political stability of Israel.** We may not be able to find or successfully bid for suitable acquisition targets or licensing opportunities, or consummate and integrate future acquisitions. **We may In addition to pursuing organic growth opportunities, we intend to continue to evaluate or and pursue potential acquisitions, strategic alliances, joint ventures, private equity, third-party financing and licenses, among other transactions, as part of our business strategy to optimize our business and product portfolio and reallocate resources to fund growth.** Relying on **such** acquisitions, licensing agreements and other transactions as sources of new innovative medicines, biosimilar and other products, or as a means of growth, involves risks that could adversely affect our future revenues and operating results. We may not be successful in seeking or consummating appropriate opportunities to enable us to execute our business strategy. We may not be able to pursue **relevant acquisitions and licensing opportunities** due to financial capacity constraints, **and** we may not be able to obtain necessary regulatory approvals, **including those of competition authorities, and as a result, or for other reasons,** we may fail to consummate an announced acquisition. We may fail to integrate acquisitions successfully into our existing business, and could incur or assume significant debt and unknown or contingent liabilities, including, among others, patent infringement or product liability claims. In addition, **we, or the partners for with** which we may enter into licensing or other collaboration agreements, may not be able to perform their responsibilities **challenging the effectively under such agreements, impairing our** ability to monetize opportunities related to them. **38** We may decide to sell, **close or otherwise divest business units, assets or facilities, which and any failure to successfully and cost-effectively consummate such divestitures** could adversely affect our prospects and opportunities for growth. We **will continue** may from time to time consider selling, **closing or otherwise divesting certain business units, assets and facilities as the focus of our business evolves, including as part of our Pivot to Growth strategy,** if we determine that such assets are not critical to our strategy or we believe the opportunity to monetize the asset is attractive or for various other reasons, including for the reduction of indebtedness. **For example, as previously announced, we intend to divest our API business in the first half of 2025, which divestiture is subject to various conditions, including reaching an agreement with a prospective purchaser on terms satisfactory to Teva, satisfying any conditions to closing the divestiture and obtaining any necessary approvals.** We **have also** closed or divested a significant number of manufacturing plants and R & D facilities **over the prior few years** in connection with our restructuring plan and may close or divest additional plants and facilities as part of our ongoing efforts regarding **network consolidation activities optimizing our business.** We have explored and may continue to explore the **There can be no assurance that we will be sale- able to complete any divestitures of certain our business units, assets or facilities, including our intended divestiture of our API business, on the timing or upon the terms we expect, if at all. Such divestitures may also divert management's attention from our core business operations, increase our expenses in the short-term and disrupt our relationships with existing employees, customers or suppliers.** We may fail to identify appropriate opportunities to divest assets on terms acceptable to us or may fail to transition employees and continuing operations from **closed sites and** disposed businesses efficiently. If divestiture opportunities are found, consummation of any such divestiture may be subject to closing conditions, including obtaining necessary regulatory approvals, **including those of competition authorities, and as a result, or for other reasons,** we may fail to consummate an anticipated divestiture. Although our expectation is to engage in asset sales only if they advance or otherwise support our overall strategy, any such sale could **result in disruptions to our business operations, result in unanticipated expenses and** reduce the size or scope of our business, the capabilities or durability of our manufacturing network, our market share in particular markets or our opportunities with respect to certain markets. **43** **If we are unable to complete our planned divestitures in a timely and cost-effective manner, or we do not realize the anticipated cost savings or other benefits of such transactions, our prospects and opportunities for growth may be negatively impacted.** Risks related to **Compliance-compliance, regulatory regulation** and litigation **risks**—Our operations are subject to complex legal and regulatory environments. If we fail to comply with applicable laws and regulations we may suffer legal consequences that may have a material effect on our business, operations or reputation. We operate around the world in complex legal and regulatory environments. **Any failure to For instance, we must comply with applicable laws-requirements of the FDA, EMA rules and regulations may result in civil and / or criminal legal proceedings and lead to fines, damages, mandatory compliance programs and other sanctions healthcare regulators with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products,** remedies that may materially affect our business and operations as **further described below** well as our reputation. In addition, as rules and regulations change or as interpretations of those rules and regulations evolve, our prior conduct may be investigated. Examples of rules and regulations impacting our operations include rules and regulations applicable to the sales and marketing of our products, competition laws, pricing laws, economic sanctions, export controls, import and trade laws and regulations, anti-bribery laws, privacy laws, compliance with cGMP, labor laws, safety and laws regarding

manufacturing practices, product labeling, advertising and post marketing reporting including adverse event reports and field alerts due to manufacturing quality concerns, tax and financial reporting laws and environmental laws. We are currently subject to several governmental and civil proceedings and litigations relating to our pricing and marketing practices, intellectual property, product liability, competition matters, opioids, securities disclosure and corporate governance and environmental matters. These investigations and litigations are costly and involve a significant diversion of management attention. Such proceedings are - We are **also** subject to extensive pharmaceutical regulation - **pricing laws, including newly- enacted state laws in the United States**, which can complex legal **impose penalties for pricing certain products above state- defined threshold, as well as competition laws, economic sanctions, export controls, import and trade** regulatory environments. If we fail to comply with applicable laws and regulations we may suffer legal consequences that may have a material effect on our business, operations or reputation. We operate around the world in complex legal **anti- bribery laws, privacy laws, cGMP requirements, labor laws** and regulatory environments **health and safety laws**. Any failure to comply with applicable laws, rules and regulations may result in civil and / or criminal legal proceedings and lead to fines, damages, mandatory compliance programs and other sanctions and remedies that may materially affect our business and operations as well as our reputation. In addition, as rules and regulations change or as interpretations of those rules and regulations evolve, our prior conduct may be investigated - be **investigated. Our** costly and subject our business **operations to disruption, delays and potential penalties**. We are subject to extensive regulation by the FDA and various other U. S. federal and state authorities, the EMA and other foreign regulatory authorities **that establish requirements relating to, among other things, manufacturing practices, product labeling, and advertising and post marketing reporting, including adverse event reports and field alerts due to manufacturing quality concerns**. The process of obtaining regulatory approvals to market a drug or medical device can be costly and time- consuming, and approvals might not be granted for future products, or additional indications or uses of existing products, on a timely basis, if at all. Delays in the receipt of, or **39** failure to obtain approvals for, future products, or new indications and uses, could result in delayed realization of product revenues, reduction in revenues and substantial additional costs. For example, in **recent the last three** years, we experienced delays in obtaining anticipated approvals for various generic and innovative medicines, **some caused by** and during 2020 and 2021 the COVID- 19 pandemic **caused some delays** in approvals due to travel and work restrictions - **During 2022, we experienced delays in regulatory approvals of new products due to reduced capacity or re- prioritization of regulatory agencies and delays in pre- commercial launch activities**. We may continue to experience similar delays. **No** In addition, no assurance can be given that we will remain in compliance with applicable FDA and other regulatory requirements once approval or marketing authorization has been obtained for a product. **Additionally** These requirements include, **our** among other things, regulations regarding manufacturing practices, product labeling, and advertising and post marketing reporting, including adverse event reports and field alerts due to manufacturing quality concerns. Our facilities are subject to ongoing regulation, including periodic inspection by the FDA and other regulatory authorities, and we must incur expense and expend effort to ensure compliance with these complex regulations. s review of our submissions, enforcement actions, injunctions and criminal prosecution. We must register our facilities, whether located in the United States or elsewhere, with the FDA for products sold in the United States, and with other regulators outside the United States for products sold outside of the United States. Our products must be produced in a manner consistent with cGMP, or similar quality and compliance standards in each territory in which we manufacture. In addition, the FDA and other agencies periodically inspect our manufacturing facilities. Following an inspection, an agency may issue a notice listing conditions that are believed to violate cGMP or other regulations, or take other regulatory action, including issuing a warning letter for violations of “ regulatory significance ” that may result in enforcement action if not promptly and adequately corrected. In recent years, regulatory agencies around the world have increased their scrutiny of pharmaceutical manufacturers. This has resulted in requests for product recalls, temporary plant shutdowns to address specific issues and other remedial actions. Our manufacturing facilities, as well as those of our vendors and manufacturing partners, have also been the subject of increased regulatory oversight, leading to increased expenditures required to ensure compliance with new or more stringent production and quality control regulations. For information regarding significant regulatory events, see note 15 to our consolidated financial statements. These regulatory actions have and may adversely **impact our ability to supply various products around the world and to obtain approvals for new products manufactured at the affected facilities. If any regulatory body were to require one or more of our significant manufacturing facilities to cease or limit production, or to halt the approval of new or pending regulatory applications, our business and reputation could be adversely affected. In addition, because regulatory approval to manufacture a drug is site- specific, the delay and cost of remedial actions or obtaining approval to manufacture at a specific facility could have a material adverse effect on our business, financial condition and results of operations.** In addition, we are subject to regulations in various jurisdictions, including the Federal Drug Supply Chain Security Act in the U. S., the Falsified Medicines Directive in the European Union and many other such regulations in other countries that require us to develop electronic systems to serialize, track, trace and authenticate units of our products through the supply chain and distribution system. Compliance with these regulations may result in increased expenses for us or impose greater administrative burdens on our organization, and failure to meet these requirements could result in fines or other penalties. Failure to comply with all applicable regulatory requirements may subject us to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, shutdown of production, revocation of approvals or the inability to obtain future approvals, or exclusion from future participation in government healthcare programs. Any of these events could disrupt our business and have a material adverse effect on our revenues, profitability and financial condition. **41 regulations impacting Governmental and civil proceedings and litigation which we are, our- or in the future become, party to may have an adverse impact on our business. In the ordinary course of our business, we are exposed to lawsuits, claims, proceedings and government investigations that could preclude or delay the commercialization of our products or disrupt our business**

operations include rules and regulations applicable. **We are currently subject to the sales several governmental and civil proceedings and litigations relating to our pricing and marketing of our practices, intellectual property, products- product liability, competition laws matters, opioids pricing laws, economic sanctions securities disclosure, export controls, import and trade laws and regulations, anti-bribery laws, privacy laws, compliance with cGMP, labor laws, safety and laws regarding manufacturing practices, product labeling, advertising and post marketing reporting including adverse event reports and field alerts due to manufacturing quality concerns, tax and financial reporting laws and accounting environmental laws.** We are currently subject to several governmental and civil proceedings and litigations relating to our pricing and marketing practices, intellectual property, product liability, competition matters, opioids, securities disclosure and corporate governance and environmental matters. These investigations and litigations are costly and involve a significant diversion of management attention. Such proceedings are unpredictable and may develop over lengthy periods of time. An adverse resolution of these proceedings may result in large monetary fines, damages, additional litigation, such as securities and derivative actions, and other non-monetary sanctions and remedies, such as mandated compliance agreements, **all of which can be expensive and disruptive to our operations and business, and can impact decisions related to our product offerings and portfolio.** **40** Due to increasing numbers of securities claims over the last several years and related payouts under insurance policies, in addition to increased settlement values in “event-driven” litigation and a growing number of plaintiff shareholder law firms eager to bring claims, premiums and deductibles for insurance, including D & O insurance, have been increasing and some insurers are reducing the number of companies they insure, causing the supply of insurance to lag behind demand. This could increase our premiums, reduce the scope and capacity of our coverage, and adversely affect our ability to maintain and renew our existing insurance policies on favorable terms or at all. While we continue to maintain insurance coverage intended to address certain risks, such coverage may be insufficient to cover claims and losses we **face.** Healthcare reforms, and related reductions in pharmaceutical pricing, reimbursement and coverage, by governmental authorities and third-party payers may adversely affect our business. The continuing increase in expenditures for healthcare has been the subject of considerable government attention almost everywhere we conduct business. Private health insurers and government health authorities continue to seek ways to reduce or contain healthcare costs, including by reducing or eliminating coverage for certain products and lowering reimbursement levels. The focus on reducing or containing healthcare costs has been fueled by controversies, political debate and publicity about prices for pharmaceutical products that some consider excessive, including Congressional and other inquiries into drug pricing, including with respect to our innovative medicines, which could have a material adverse effect on our reputation. In most of the countries and regions where we operate, including the United States, Western Europe, Israel, Russia, Japan, certain countries in Central and Eastern Europe and several countries in Latin America, pharmaceutical prices are subject to new government policies designed to reduce healthcare costs, and may be subject to additional regulatory efforts, funding restrictions, legislative proposals, policy interpretations, investigations and legal proceedings regarding pricing practices. These changes frequently adversely affect pricing and profitability and may cause delays in market entry, or decisions to forgo or discontinue development programs for our products. Certain U. S. states have implemented or are considering, pharmaceutical price controls or patient access constraints under the Medicaid program, and some jurisdictions have implemented or are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. Private third-party payers, such as health plans, increasingly challenge pharmaceutical product pricing, which could result in lower prices, lower reimbursement rates and a reduction in demand for our products. We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our products, which could have a material adverse effect on our business, financial condition and results of operations. The U. S. Congress and various state legislatures in the United States continue to propose and enact legislative reforms to limit or reduce the cost of healthcare and regulate drug pricing practices. For example, the IRA introduced certain measures that, among other things, limit the price increases of prescription drugs and authorize the Medicare program to negotiate pricing for certain high-cost drugs, including physician-administered and self-administered drugs, that have been on the market for a minimum amount of time without generic competition. The IRA also includes reforms to Medicare benefit design, increasing a manufacturer’s coverage liability for applicable products. As the IRA was only recently enacted, we cannot accurately predict the impact it will have on the profitability of our products or our research and development initiatives. A number of state legislatures have also begun considering legislation that would implement IRA-like frameworks for state regulated insurance markets. **The pharmaceutical industry faces uncertainty regarding future pharmaceutical pricing changes. For example, on November 27, 2020 the CMS published an Interim Final Rule (“IFR”) that would have imposed a mandatory Most Favored Nation (“MFN”) pricing model on the fifty single-source drugs and biologics (including biosimilars) with the highest annual Medicare Part B spending for seven years, beginning January 1, 2021. The MFN model would have ultimately based payment for each of the fifty drugs on the lowest-available, gross domestic product (“GDP”) adjusted drug price available in any Organization for Economic Co-operation and Development (“OECD”) country that meets minimum GDP requirements. Pharmaceutical and biotechnology industry organizations as well as several patient support groups filed litigation to enjoin implementation of the IFR. On December 28, 2020, the U. S. District Court for the Northern District of California imposed a nationwide preliminary injunction on implementation of the IFR pending CMS’ s completion of regulatory notice-and-comment rulemaking by CMS. On December 29, 2021, CMS published a final rule that rescinded the IFR, effective February 28, 2022, to address the procedural issues acknowledged in the preliminary injunction. Although the IFR as published will not go into effect, CMS could propose future pharmaceutical pricing changes similar to the IFR, albeit with the required notice and opportunity for stakeholders to participate in the regulatory process.** Increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries may result in increased pricing pressure by influencing the reimbursement policies of third-party **42** payers. Healthcare reform legislation has increased the number of patients who have insurance coverage for our products, but provisions such as the assessment of a branded pharmaceutical manufacturer fee and an increase in the amount of

rebates that manufacturers pay for coverage of their drugs by Medicaid programs may have an adverse effect on us. It is uncertain how current and future reforms in these areas will influence the future of our **41** business operations and financial condition. In addition, “ tender systems ” for generic pharmaceuticals have been implemented (by both public and private entities) in a number of significant markets in which we operate, including in some European markets, in an effort to lower prices. Under such tender systems, manufacturers submit bids that establish prices for generic pharmaceutical products. These measures impact marketing practices and reimbursement of drugs and may further increase pressure on reimbursement margins. Certain other countries may consider the implementation of a tender system. Failing to win tenders or our withdrawal from participating in tenders, or the implementation of similar systems in other markets leading to further price declines, could have a material adverse effect on our business, financial position and results of operations. **A significant portion of our revenues is..... cover claims and losses we face.** Public concern over the abuse of opioid medications, increased legal and regulatory action and ~~any delay in our ability to obtain sufficient participation of plaintiffs for the nationwide settlement to take effect,~~ could negatively affect our business. Certain governmental and regulatory agencies are focused on the abuse of opioid medications in the United States. U. S. federal, state and local governmental and regulatory agencies ~~are~~ **have conducted and may in the future conducting --- conduct** investigations of us, other pharmaceutical manufacturers and other supply chain participants with regard to the manufacture, sale, marketing and distribution of opioid medications. ~~We currently are litigating civil~~ **In June 2023, we consummated a nationwide settlement to settle** claims and administrative actions brought by various states and political subdivisions ~~as well as private claimants, against various manufacturers, distributors and retail pharmacies throughout the United States~~ in connection with our manufacture, marketing, sale and distribution of opioids. **The payments required to be made under this** ~~In November 2022, we finalized the documentation of our nationwide settlement agreement , which is contingent upon reaching sufficient participation by states and subdivisions. There is no assurance as to when or whether such sufficient participation can be obtained, and based on experience with the nationwide settlements of other- others defendants in these matters, we do not expect 100 percent participation by all states and subdivisions. Additionally, once finalized, settlement payments that we will be required to make,~~ may have an adverse impact on our operations and cash flows and there is no assurance that we will have the liquidity or other resources necessary to make such payments and provide supplies of our generic ~~44~~ version of Narcan ® (naloxone hydrochloride nasal spray) in the amounts and at the times required under the terms of our nationwide settlement **settlements** . Moreover, if we are unable to reach an agreement with any remaining states and subdivisions, we will continue to litigate these cases and may face a material adverse judgment . For further information, see “ Opioids Litigation ” in note 12b to our consolidated financial statements. Additionally, we are defending claims and putative class action lawsuits in Canada in relation to the manufacture, sale, marketing and distribution of opioid medications. The loss or settlement of any such claims related to opioids could have a material adverse impact on our liquidity. In addition to the costs and potential consequences associated with defending the governmental investigations and legal proceedings, legislative, regulatory or industry measures to address the misuse of prescription opioid medications may also affect our business in ways that we are not able to predict. For example, a number of states, including New York, have enacted legislation that requires the payment of assessments or taxes on the sale or distribution of opioid medications in those states. If other states or local jurisdictions successfully enact similar legislation and we are not able to mitigate the impact on our business through operational changes or commercial arrangements, such legislation in the aggregate may have a material adverse effect on our business, financial condition and results of operations. Furthermore, we utilize controlled substances in certain of our current products and products in development, and therefore must meet the requirements of the Controlled Substances Act of 1970 and related regulations administered by the DEA in the U. S. , as well as the requirements of similar laws and regulations in other countries where we operate, relating to the manufacture, importation, shipment, storage, sale, and use of controlled substances. **While we** ~~We are committed to compliance and have robust~~ compliance systems in place ; ~~however,~~ risks associated with these laws and regulations cannot be entirely eliminated by policies and procedures. For example, violations of the Controlled Substances Act of 1970 and related laws and regulations by **direct customers third-party intermediaries (such as distributors and wholesalers) , down- stream customers (such as pharmacies) and health- care providers** may expose us to liability and penalties and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and / or share price. In addition, prescription drug abuse and the diversion of opioids and other controlled substances are the frequent subject of public attention, including, for example, ~~recent past~~ media reports over the appropriateness of prescription of medications used to treat attention deficit hyperactivity disorder (ADHD). The occurrence of any of the above risks could have a material adverse effect on our business, financial condition, **reputations,** results of operations, cash flows , ~~and / or share price.~~ **42** The pharmaceutical sector is facing increased government scrutiny from competition and pricing authorities around the world, which may expose us to significant damages and commercial restrictions that can materially and adversely affect our business. We are required to comply with competition laws in the territories where we do business around the world. Compliance with these laws has been the subject of increasing focus and activity by regulatory authorities, both in the United States and Europe, in recent years. Alleged actions by our employees, in violation of such laws, or evolving interpretations of competition law as applicable to certain practices, have exposed us, and may further expose us, to investigations and legal proceedings, which may result in significant liability for violations of competition laws, which may have a material adverse effect on our reputation, business, financial condition and results of operations. We ~~are~~ **have been and may in the future be** subject to a DOJ civil investigation **investigations , claims and a criminal indictment charging Teva USA with criminal felony proceedings relating to price fixing and violations of related laws and regulations, such as the Sherman Act violations.** **In August 2023 , we reached a deferred prosecution agreement with the DOJ to settle certain price- fixing charges brought against us in 2020. In addition, we are a party to numerous civil claims brought by state officials and private plaintiffs alleging that Teva , if resulting together with other pharmaceutical manufacturers, engaged in a conviction-conspiracies to fix prices and / or allocate market share of generic products in the United States. or For guilty plea further information , could have a see “**

Government Investigations and Litigation Relating to Pricing and Marketing” in note 12b to our consolidated financial statements. If any investigations, claims or proceedings are adversely determined against us, we may face material adverse **effect effects** on our business, including monetary penalties, debarment from federally funded health care programs and reputational harm. ~~In addition, we are a party to numerous civil claims brought by state officials and private plaintiffs alleging that Teva, together with other pharmaceutical manufacturers, engaged in conspiracies to fix prices and / or allocate market share of generic products in the United States. For further information, see “ Government Investigations and Litigation Relating to Pricing and Marketing ” in note 12b to our consolidated financial statements.~~ 45 We have been involved in numerous litigations involving challenges to the validity or enforceability of listed patents (including our own), and therefore settling patent litigations has been and will likely continue to be an important part of our business. There is continued scrutiny of our patent settlements, including from the U. S. Federal Trade Commission (“ FTC ”) and the European Commission. Accordingly, we may receive formal or informal requests from competition law authorities around the world for information about a particular settlement agreement, and there is a risk that governmental authorities, customers, other downstream purchasers or others may commence actions against us alleging violations of antitrust laws based on our settlement agreements. We are currently defendants in antitrust actions brought by U. S. states, the European Commission and private plaintiffs involving numerous settlement agreements and, since 2015, we are subject to a consent decree with the FTC, which imposes on us certain injunctive reliefs with respect to our ability to enter into patent settlements in the United States. The U. S. Congress and certain state legislatures in the United States have also passed, or proposed passing, legislation that could adversely impact our ability to settle patent litigations. For example, the State of California has enacted legislation that prohibits, with certain exceptions and safe harbors, various types of patent litigation settlements, and imposes substantial monetary penalties on companies and individuals who do not comply. The enforcement of this law has been preliminarily enjoined as likely violating the U. S. Constitution, but such legislation still creates a risk of significant potential exposure for settling patent litigations and, in turn, makes it more difficult to settle in the first place, which could have a material adverse effect on our business. Following calls in recent years from policy makers and other stakeholders in many countries for governmental intervention to address the high prices of certain pharmaceutical products, we are currently, and may in the future be, subject to governmental investigations, claims or other legal or regulatory actions regarding our pricing and / or other alleged exclusionary practices. These include U. S. Congressional investigations regarding both our innovative medicines and generic medicines, the European Commission’s inquiry into COPAXONE, and litigation concerning the U. K. Competition and Markets Authority’s inquiry regarding hydrocortisone. For example, in September 2020, the U. S. House Committee on Oversight and Reform held a hearing focused on pricing of branded medications, which focused in part on historic pricing of COPAXONE in the U. S., and subsequently issued a report with respect to COPAXONE’s pricing. Additionally, on October 10, 2022, the European Commission issued a Statement of Objections, which sets forth its preliminary allegations that Teva had engaged in anti-competitive practices relating to COPAXONE. **It is not possible to predict. In November 2023, the FTC notified Teva and the other ultimate outcome pharmaceutical companies as well as the FDA, under 21 CFR 314.53, that in the FTC’s view, certain of any our and other pharmaceutical companies’ patents have been improperly listed in the Orange 43 Book, resulting in potential delays to generic competition, and subsequently, certain members of the U. S. congress reiterated the concerns of the FTC. Any such investigations- investigation ;** ~~claims or proceedings or what other investigations or lawsuits or regulatory responses may result from such assertions, which could~~ have a material adverse effect on our reputation, business, financial condition and results of operations. For further information, see “ Competition Matters ” and “ Government Investigations and Litigation Relating to Pricing and Marketing ” in note 12b to our consolidated financial statements. Third parties may claim that we infringe their intellectual property rights and we may have sold or may in the future elect to sell products prior to the final resolution of outstanding intellectual property litigation, and, as a result, we may be prevented from manufacturing and selling some of our products and could be subject to liability for damages in the United States, Europe and other markets where we do business. Our ability to introduce new products depends in large part upon the success of our challenges to patent rights held by third parties or our ability to develop non- infringing products. Based upon a variety of legal and commercial factors, we may elect to sell a product even though patent litigation is still pending, either before any court decision is rendered or while an appeal of a lower court decision is pending. The outcome of such patent litigation could, in certain cases, materially adversely affect our business. For further information, see “ Intellectual Property Litigation ” in note 12b to our consolidated financial statements. If we sell products prior to a final court decision, and such decision is adverse to us, we could be required to cease selling the infringing products, causing us to lose future sales revenue from such products and we could face substantial liabilities for patent infringement, in the form of either payment for the innovator’s lost profits or a royalty on our sales of the infringing products. These damages may be significant and could materially ~~adversely~~ affect our business. In the United States, in the event of a finding of willful infringement, the damages assessed may be up to three times the profits lost by the patent owner. Because of the discount pricing typically involved with generic pharmaceutical products, patented brand products generally realize a significantly higher profit margin than generic pharmaceutical products. As a result, the damages assessed may be significantly higher than our profits. In addition, even if we do not suffer damages, we may incur significant legal and related expenses in the course of successfully defending against infringement claims. We may be susceptible to significant product liability claims that are not covered by insurance. Our business inherently exposes us to claims for injuries allegedly resulting from the use of our products. As our portfolio of available products expands, particularly with new innovative medicines, we may experience increases in product liability claims asserted against us. We maintain an insurance program, which may include commercial insurance, self- insurance (including direct risk retention), or a combination of both approaches, in amounts and on terms that it believes are reasonable and prudent in light of its business and related risks. We sell, and will continue to sell, pharmaceutical products that are not covered by ~~its~~ product liability insurance. In addition, we may be subject to claims for which insurance coverage is denied, as well as claims that exceed our policy limits. Product liability coverage for

pharmaceutical companies is becoming more expensive and increasingly difficult to obtain. As a result, we may not be able to obtain the type and amount of insurance we desire, or any insurance on reasonable terms, in the markets in which we operate. For further information regarding our current material product liability cases, see note 12b to our consolidated financial statements. Any failure to comply with the complex reporting and payment obligations under the Medicare and Medicaid programs may result in further litigation or sanctions, in addition to those that we have announced in previous years. The U. S. laws and regulations regarding Medicare and / or Medicaid reimbursement and rebates and other governmental programs are complex. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. The subjective decisions and complex methodologies used in making calculations ~~44~~ under these programs are subject to review and challenge, and it is possible that such reviews could result in material changes. In addition, the U. S. government has alleged violations of the federal Anti- Kickback Statute, and related causes of action under the federal False Claims Act and state law in connection with Teva’ s donations to patient assistance programs. Such allegations could, if proven or settled, result in additional monetary penalties (beyond the lawsuits we have already settled) and possible exclusion from Medicare, Medicaid and other programs. In addition, we are notified from time to time of governmental investigations regarding drug reimbursement or pricing issues. For further information, see “ Government Investigations and Litigation Relating to Pricing and Marketing ” in note 12b to our consolidated financial statements. Certain parts of Medicare benefits are under scrutiny, as the U. S. Congress looks for ways to reduce government spending on prescription medicines. Sanctions and trade control laws create the potential for significant liabilities, penalties and reputational harm. As a company with global operations, we ~~are may be~~ subject to national laws as well as international treaties and conventions controlling imports, exports, re- export, transfer and diversion of goods (including finished goods, materials, APIs, packaging materials, other products and machines), services and technology. These include import and customs laws, export controls, trade embargoes and economic sanctions, restrictions on sales to parties that are listed on (or are owned or controlled by one or more parties listed on) denied party watch lists and anti- boycott measures (collectively “ Customs and Trade Controls ”). Applicable Customs and Trade Controls are administered by Israel’ s Ministry of Finance, the U. S. Treasury’ s Office of Foreign Assets Control, the U. S. Department of Commerce, other U. S. agencies and multiple other agencies of other jurisdictions around the ~~47~~ world where we do business. Customs and Trade Controls relate to a number of aspects of our business, including most notably the sales of finished goods and API as well as the licensing of our intellectual property. Compliance with Customs and Trade Controls has been the subject of increasing focus and activity by regulatory authorities, both in the United States and elsewhere, in recent years, and requirements under applicable Customs and Trade Controls in general, change frequently. Sanctions imposed with respect to the ongoing conflict between Russia and Ukraine have been particularly dynamic and future geopolitical conflicts involving other jurisdictions may result in further changes to the sanctions environment. Any such changes to the sanctions environment may require us to withdraw from or limit our exposure to certain markets or to terminate certain business relationships in order to remain in compliance with applicable laws. Although we have policies and procedures designed to address compliance with Customs and Trade Controls, actions by our employees, by third- party intermediaries (such as distributors and wholesalers) or others acting on our behalf in violation of relevant laws and regulations may expose us to liability and penalties for violations of Customs and Trade Controls and accordingly may have a material adverse effect on our reputation and our business, financial condition and results of operations. Our failure to comply with applicable environmental, health and safety laws and regulations worldwide could adversely impact our business and results of operations. We are subject to laws and regulations concerning the environment, safety matters, regulation of chemicals and product safety in the countries where we manufacture and sell our products or otherwise operate our business. These requirements include regulation of the handling, manufacture, transportation, storage, use and disposal of materials, including the discharge of pollutants and pharmaceutical residues into the environment. If we fail to comply with these laws and regulations, we may be subject to enforcement proceedings including fines and penalties. In the normal course of our business, we are also exposed to risks relating to possible releases of hazardous substances into the environment, which could cause environmental or property damage or personal injuries, and which could require remediation of contaminated soil and groundwater. Under certain laws, we may be required to remediate contamination at certain properties, regardless of whether the contamination was caused by us or by previous occupants or users of the property. Climate change, and evolving laws, regulations and policies regarding climate change, could also pose additional legal or regulatory requirements related to greenhouse gas (“ GHG ”) emissions and climate risk reporting, carbon pricing, and mandatory reduction targets. These more stringent requirements could increase our costs of sourcing, production, and transportation, as well as ~~45~~ have negative reputational impacts if we fail to meet such requirements. While we have validated Science- Based Targets for GHG reductions, failure to respond to risks regarding climate change may have a material adverse effect on our business, financial condition, results of operations and reputation. The consequences of climate change, such as extreme weather and water scarcity, could pose risks to our facilities and disruption of our activities. Natural disasters and extreme weather events resulting from climate change, such as floods, heatwaves, blizzards, hurricanes, wildfires, the rise of sea level, and water stress, could impact our business activities and our ability to deliver our products to customers. We evaluate these risks in our supply planning, loss prevention and business continuity planning. The implementation of an Environmental, Health and Safety Management System across our facilities has resulted in the development of processes to prepare and respond to a range of natural emergencies that may occur, including extreme weather events. We have been placing increased attention on water management, implementing a scarcity- focused approach to water conservation to align with community needs and advance toward sustainable operations. If our planning and risk management regarding natural disasters and extreme weather events fail, our facilities could be impacted and our activities could be significantly disrupted. Our business could be negatively impacted by ESG issues. In recent years, there has been an increased focus from certain investors, employees, consumers, regulators (including the SEC), and other stakeholders concerning ESG matters. These matters can contribute to the long- ~~48~~ term sustainability of companies’ performance and an inability to successfully perform on ESG matters can result in negative impacts to our reputation,

recruitment, retention, operations, financial results, the price of our shares, and our ability to attract or retain certain types of customers and investors. From time to time, we announce certain initiatives, including goals, regarding our focus areas, which include environmental matters, responsible procurement, promoting access to medicines, social investments, compliance and ethics and I & D. We could fail, or be perceived to fail, either in identifying our ESG focus areas, or in our achievement of our initiatives or goals, whether described in our announcements, our ESG progress report or otherwise, or we could fail to accurately report our progress on such initiatives and goals. Such failures could be due to changes in our business or evolving regulations in the countries in which we operate, and any such failures or perceived failures could expose us to negative impacts, including government enforcement actions or private litigation. We have also issued sustainability-linked senior notes with targets that include improving access to medicines in low- and middle- income countries and reducing GHG emissions, and failure to achieve such targets could negatively impact our reputation and also result in increased payments to holders of such senior notes. A variety of organizations measure performance on ESG topics, including on topics such as the cost, even if unintended, of our actions on climate change and inequality in society. We could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly or far enough in connection with these matters. Any such ESG matters could have a material adverse effect on our reputation, business, financial condition and results of operations. Additionally, companies across a variety of industries, including the pharmaceutical industry, are experiencing increased shareholder activism regarding ESG matters. If we are required to respond to actions by activist shareholders, we could incur disruptions to the operation of our business and our management's attention could be diverted. While we monitor a broad range of ESG issues, there can be no certainty that we will manage such issues successfully, or that we will successfully meet the expectations of investors, employees, consumers and other stakeholders. Moreover, our selection of disclosure frameworks that seek to align with various reporting standards may change from time to time and may result in lack of meaningful or comparative data from period to period. Our interpretation of reporting standards may differ from those of others and such standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals. Collecting, measuring, and reporting ESG information and metrics can be costly, difficult and time consuming, is subject to evolving reporting standards, and can present numerous operational, reputational, financial, legal and 46 other risks, any of which could have a material impact, including on our business, financial condition, reputation and stock price. Inadequate processes to collect and review this data and information prior to disclosure could be subject to potential liability related to such information.

Furthermore, there are an increasing number of ESG-related regulatory disclosure regulations with which Teva may have to comply. For example, in December 2022, the European Union adopted Directive No 2464 / 2022 on Corporate Sustainability Reporting (“ CSRD ”). The CSRD introduces detailed sustainability reporting obligations, requiring in-scope companies to make sustainability reports in accordance with the European Sustainability Reporting Standards (“ ESRS ”), which include certain mandatory disclosures and other voluntary disclosures on impacts, risks, and opportunities in relation to sustainability matters identified as material by the relevant entity. In addition, addition to assessing the financial effects of a sustainability matter on a company, materiality assessments will require the relevant company to take into account non-financial considerations as to the materiality of a sustainability matter from an impact perspective when it pertains to the undertaking's actual or potential, positive or negative impacts on people or the environment over the short-, medium- or long-term. Impacts may include those connected with the company's own operations and upstream and downstream value chain, including through its products and services, as well as through its business relationships. Teva expects to first have to disclose pursuant to the CSRD, in accordance with the ESRS, in 2026. Furthermore, Article 8 of Regulation (EU) 2020 / 852 (EU Taxonomy) requires those in-scope companies to report how and to what extent their activities are associated with economic activities that qualify as environmentally sustainable defined herein. This disclosure obligation may lead to increased compliance burdens and costs. Additionally, could lead to the disclosure of information which may have a negative impact on our operations and reputation, and which may lead to additional exposure. Failure to accurately comply with any ESG reporting obligations may result in enforcement actions, sanctions, reputational harm or private litigation.

Risks Related to our financial condition Because we have substantial international operations, our sales, profits and cash flow may be adversely affected by currency fluctuations and restrictions as well as credit risks. Fluctuations in exchange rates between the currencies in which we operate in, and the U. S. dollar, may have a material adverse effect on our results of operations, the value of balance sheet items denominated in foreign currencies and our financial condition. In 2022-2023, approximately 47 % of our revenues were denominated in currencies other than the U. S. dollar. As a result, we are subject to significant foreign currency risks, including repatriation restrictions in certain countries, and may face heightened risks as we enter new markets. A substantial proportion of our sales, particularly in Latin America, Central and Eastern European countries and Asia, are recorded in local currencies, which exposes us to the direct risk of devaluations, hyperinflation or exchange rate fluctuations. In addition, although the majority of our operating costs are recorded in, or linked to, the U. S. dollar, in 2022-2023, we incurred a substantial amount of operating costs in currencies other than the U. S. dollar, which only partially offset the currency risk derived from our sales in non- U. S. dollars. Moreover, the strengthening of the U. S. dollar versus other currencies in which we operate, negatively impacted our revenues, results of operations, profits and cash flows. 49-We use derivative financial instruments and “ hedging ” techniques, such as issuance of debt in non- U. S. dollar currencies, to manage our balance sheet and income statement exposure to currency exchange rate fluctuations in the major foreign currencies in which we operate. However, not all of our potential exposure is covered, and some elements of our consolidated financial statements, such as our equity position, are not protected against foreign currency exposures. Therefore, our exposure to exchange rate fluctuations could have a material adverse effect on our financial results. The imposition of price controls or restrictions on the conversion of foreign currencies could also have a material adverse effect on our financial results. In addition, operating internationally exposes us to credit risks of customers and other counterparties in a number of jurisdictions. Some of these customers and other counterparties may have lesser creditworthiness than others and the

legal system for enforcing collections in such jurisdictions may be less well- developed. **47** Our long- lived assets may continue to lead to significant impairments in the future. We regularly review our long- lived assets, including identifiable intangible assets, goodwill and property, plant and equipment, for impairment. Goodwill and acquired indefinite life intangible assets are subject to impairment review on an annual basis and whenever potential impairment indicators are present. Other long- lived assets are reviewed when there is an indication that impairment may have occurred. The amount of goodwill, identifiable intangible assets and property, plant and equipment on our consolidated balance sheet may increase following acquisitions or other collaboration agreements. Changes in market conditions, including further increases in discount rates, exchange rate fluctuations, or other changes in the future outlook of value may lead to further impairments in the future. In addition, the potential divestment of assets, including the closure or divestment of manufacturing plants and R & D facilities, headquarters and other office locations, may lead to additional impairments. Future events or decisions may lead to asset impairments and / or related charges. For assets that are not impaired, we may adjust the remaining useful lives. Certain non- cash impairments may result from a change in our strategic goals, business direction or other factors relating to the overall business environment. Any significant impairment could have a material adverse effect on our results of operations. See notes 6 and 7 in our consolidated financial statements, for descriptions of impairments of intangible assets and goodwill in recent periods. Our tax liabilities could be larger than anticipated. We are subject to tax in many jurisdictions, and significant judgment is required in determining our provision for income taxes. Likewise, we are subject to audit by tax authorities in many jurisdictions. In such audits, our interpretation of tax legislation may be challenged and tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions under our inter- company agreements. Although we believe our estimates are reasonable, the ultimate outcome of such audits and related litigation could be different from our provision for taxes and may have a material adverse effect on our consolidated financial statements and cash flows. For additional information see note 13 to our consolidated financial statements. The base erosion and profit shifting (“ BEPS ”) project undertaken by the **Organization for Economic Co- operation and Development (“ OECD ”)** may have adverse consequences to our tax liabilities. The BEPS project contemplates changes to numerous international tax principles, as well as national tax incentives, and these changes, when adopted by individual countries, could adversely affect our provision for income taxes. The first wave of BEPS recommendations has been implemented by countries in specific national tax laws, and the OECD is currently working on further initiatives that may further change current international tax principles. On December 12, 2022, the EU Council announced that EU member states had reached an agreement to implement at EU level the minimum taxation component of 15 % (“ Pillar Two ”) of the OECD’ s reform of international taxation , **commencing in 2024** . We are currently monitoring the new rules and awaiting further guidance and country agreements, however **it remains difficult to predict, we do not expect the magnitude adoption of the effect of such new rules this guidance to have a material impact on our the Company’ s consolidated financial results statements in the foreseeable future** . **50** The termination or expiration of governmental programs or tax benefits, or a change in our business, could adversely affect our overall effective tax rate. Our tax expenses and the resulting effective tax rate reflected in our consolidated financial statements may increase over time as a result of changes in corporate income tax rates, other changes in the tax laws of the various countries in which we operate or changes in our product mix or the mix of countries where we generate profit. We have benefited, and currently benefit, from a variety of Israeli and other government programs and tax benefits that generally carry conditions that we must meet in order to be eligible to obtain such benefits. If we fail to meet the conditions upon which certain favorable tax treatment is based, we would not be able to claim future **48** tax benefits and could be required to refund tax benefits already received. Additionally, some of these programs and the related tax benefits are available to us for a limited number of years, and these benefits expire from time to time. Any of the following could have a material effect on our overall effective tax rate: **↔**some government programs may be discontinued, or the applicable tax rates may increase; **↔**we may be unable to meet the requirements for continuing to qualify for some programs and the restructuring plan may lead to the loss of certain tax benefits we currently receive; **↔**these programs and tax benefits may be unavailable at their current levels; **↔**upon expiration of a particular benefit, we may not be eligible to participate in a new program or qualify for a new tax benefit that would offset the loss of the expiring tax benefit; or **↔**we may be required to refund previously recognized tax benefits if we are found to be in violation of the stipulated conditions. **Failure to establish and maintain effective internal control over financial reporting could have a material adverse effect on our ability to report our financial condition, results of operations, or cash flows accurately and on a timely basis and could harm our reputation. As a publicly traded company, we are subject to the Securities Exchange Act of 1934 (the “ Exchange Act ”) and the Sarbanes- Oxley Act of 2002 (“ Sarbanes- Oxley Act ”). The Sarbanes- Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. As part of its annual review of the effectiveness of Teva’ s internal control over financial reporting as of December 31, 2023, management identified a material weakness in our internal control over financing reporting. The identified material weakness will be considered remediated once additional internal controls are designed, implemented and operate effectively for a sufficient period of time to allow management to conclude that the material weakness has been fully remediated. However, there is no assurance as to when we will be able to fully remediate the identified material weakness or if additional material weaknesses will be identified. Any failure to implement remedial measures and to achieve and maintain effective internal control over financial reporting could have a material adverse effect on the market for our ordinary shares. For a discussion of our internal control over financial reporting and a description of the identified material weakness and remediation plan, see “ Part II, Item 9A. Controls and Procedures ” of this Annual Report on Form 10- K. Risks related to Equity- equity ownership risks** Shareholder rights and responsibilities as a shareholder are governed by Israeli law, which differs in some material respects from the rights and responsibilities of shareholders of U. S. companies. The rights and responsibilities of the holders of our ordinary shares are governed by our articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of

shareholders of U. S. corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising his or her rights and performing his or her obligations towards the company and other shareholders, and to refrain from abusing his or her power in the company, including, among other things, in voting at a general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. ~~There is limited case law available to assist in understanding the nature of this duty or the implications of these provisions.~~ These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U. S. corporations. Provisions of Israeli law and our articles of association may delay, prevent or make difficult an acquisition of us, prevent a change of control and negatively impact our share price. Israeli corporate law regulates acquisitions of shares through tender offers and mergers, requires special approvals for transactions involving directors, officers or significant shareholders, and regulates other matters **49** that may be relevant to these types of transactions. Furthermore, ~~Israeli tax considerations may make potential acquisition transactions unappealing to us or to some of our shareholders. For example, Israeli tax law may subject a shareholder who exchanges his or her ordinary shares for shares in a foreign corporation to taxation before disposition of the investment in the foreign corporation. These provisions of Israeli law may delay, prevent or make difficult an acquisition of our company, which could prevent a change of control and, therefore, depress the price of our shares.~~ 51