

The FDA Amendments Act of 2007 imposed additional obligations on pharmaceutical companies and delegated more enforcement authority to the FDA in the area of drug safety. Key elements of this legislation give the FDA authority to (i) require that companies conduct post-marketing safety studies of drugs, (ii) impose certain safety related drug labeling changes, (iii) mandate risk mitigation measures such as the education of healthcare providers and the restricted distribution of medicines, (iv) require companies to publicly disclose data from clinical studies and (v) pre-review television advertisements.

The marketing practices of all U.S. pharmaceutical manufacturers are subject to Federal and state healthcare laws that are used to protect the integrity of government healthcare programs. The Office of Inspector General (“OIG”) oversees compliance with applicable Federal laws, in connection with the payment for products by government funded programs, primarily Medicaid and Medicare. These laws include the Federal anti-kickback statute, which criminalizes knowingly offering something of value to induce the recommendation, order or purchase of products or services reimbursed under a government healthcare program. The OIG has issued a series of guidances to segments of the healthcare industry, including the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers, which includes a recommendation that pharmaceutical manufacturers, at a minimum, adhere to the PhRMA Code, a voluntary industry code of marketing practices. We subscribe to the PhRMA Code and have implemented a compliance program to address the requirements set forth in the guidance and our compliance with the healthcare laws. Failure to comply with these healthcare laws could subject us to administrative and legal proceedings, including actions by Federal and state government agencies. Such actions could result in the imposition of civil and criminal sanctions, which may include fines, penalties and injunctive remedies; the impact of which could materially adversely affect our business, financial condition and results of operations and cash flows.

We are also subject to the jurisdiction of various other Federal and state regulatory and enforcement departments and agencies, such as the Federal Trade Commission, the Department of Justice and the Department of Health and Human Services in the U.S. We are also licensed by the U.S. Drug Enforcement Administration to procure and produce controlled substances. We are, therefore, subject to possible administrative and legal proceedings and actions by these organizations. Such actions may result in the imposition of civil and criminal sanctions, which may include fines, penalties and injunctive or administrative remedies.

The U.S. healthcare industry is subject to various government-imposed regulations authorizing prices or price controls that have and will continue to have an impact on our total revenues. We participate in state government Medicaid programs, as well as certain other qualifying Federal and state government programs whereby discounts and rebates are provided to participating state and local government entities. We also participate in federal government programs that specify discounts to certain federal government entities; the most significant of which are the U.S. Department of Defense and the U.S. Department of Veterans Affairs. These entities receive minimum discounts based off a defined “non-federal average manufacturer price” for purchases.

As a result of HR 3590 (Affordable Care Act) and the reconciliation bill containing a package of changes to the healthcare bill, we have and will continue to experience additional financial costs and certain other changes to our business. For example, we are required to provide a 70% discount on our brand-name drugs to patients who fall within the Medicare Part D coverage gap, also referred to as the “donut hole”, and pay an annual non-tax-deductible fee to the federal government based on an allocation of our market share of branded drug sales to certain government programs including Medicare, Medicaid, Department of Veterans Affairs, Department of Defense and TRICARE. The amount of the annual fee imposed on pharmaceutical manufacturers as a whole is \$2.8 billion for 2019 and thereafter.

Our activities outside the U.S. are also subject to regulatory requirements governing the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of our products. These regulatory requirements vary from country to country. Whether or not FDA or EC approval has been obtained for a product, approval of the product by comparable regulatory authorities of countries outside of the U.S. or the EU, as the case may be, must be obtained prior to marketing the product in those countries. The approval process may be more or less rigorous from country to country and the time required for approval may be longer or shorter than that required in the U.S. Approval in one country does not assure that a product will be approved in another country.

For further discussion of these rebates and programs, refer to “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations—GTN Adjustments” and “—Critical Accounting Policies.”

### **Sources and Availability of Raw Materials**

In general, we purchase our raw materials, components and supplies required for the production of our products in the open market. For some products, we purchase our raw materials, components and supplies from one source (the only source available to us) or a single source (the only approved source among many available to us), thereby requiring us to obtain such raw materials and supplies from that particular source. We attempt, if possible, to mitigate our potential risk associated with our raw materials, components and supplies through inventory management and alternative sourcing strategies. For further discussion of sourcing, refer to “—Manufacturing and Quality Assurance” below and discussions of particular products.