

## RISK FACTORS

### Risks Associated with Teva and the Pharmaceutical Industry

***Our success depends on our ability to successfully develop and commercialize additional pharmaceutical products.***

Our future results of operations depend, to a significant degree, upon our ability to successfully commercialize additional generic and/or innovative branded pharmaceutical products. We must develop, test and manufacture generic products as well as prove that our generic products are the bio-equivalent of their branded counterparts. All of our products must meet regulatory standards and receive regulatory approvals. The development and commercialization process, particularly with respect to innovative products, 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 obtained in a timely manner, if at all, and such products may not be able to be successfully and profitably produced and marketed. Delays in any part of the process or our inability to obtain regulatory approval of our products (including the products filed by IMPAX Laboratories Inc. and Biovail Corporation for which we have exclusive marketing rights in the U.S.) could adversely affect our operating results by restricting our introduction of new products. The continuous introduction of new generic products is critical to our business.

***Our revenues and profits from any particular generic pharmaceutical products decline as our competitors introduce their own generic equivalents.***

Selling prices of generic drugs typically decline, sometimes dramatically, as additional companies receive approvals for a given product and competition intensifies. To the extent that we succeed in being the first to market a generic version of a significant product, our sales and profitability can be substantially increased in the period following the introduction of such product and prior to a competitor's introduction of the equivalent product. Our ability to sustain our sales and profitability on any product over time is dependent on both the number of new competitors for such product and the timing of their approvals. Our overall profitability depends on our ability to continuously and timely introduce new products.

***Our generic pharmaceutical products face intense competition from brand-name companies that sell their own generic products or successfully extend their market exclusivity period.***

Competition in the U.S. generic pharmaceutical market continues to intensify as the pharmaceutical industry adjusts to increased pressures to contain health care costs. Brand-name companies continue to sell their products into the generic market directly by acquiring or forming strategic alliances with generic pharmaceutical companies. No regulatory approvals are required for a brand-name manufacturer to sell directly or through a third party to the generic market. Brand-name manufacturers do not face any other significant barriers to entry into such market. In addition, such companies continually seek new ways to defeat generic competition, such as filing new patents on drugs whose original patent protection is about to expire, developing patented controlled-release products, changing product claims and product labeling or developing and marketing as over-the-counter products those branded products which are about to face generic competition.

***Recent changes in the regulatory environment may prevent us from exploiting the exclusivity periods that are critical to the success of our generic products.***

The FDA's policy regarding the award of 180-days market exclusivity to generic manufacturers who challenge patents relating to specific products continues to be the subject of much litigation in the United States. The FDA's current interpretation of the Waxman-Hatch Act is to award 180 days of exclusivity to the first generic manufacturer who files a Paragraph IV certification under the Act challenging the patent of the branded product, regardless of whether the manufacturer was sued for patent infringement. Although the FDA's interpretation may benefit some of the products in our pipeline, it may adversely affect others.

The Waxman-Hatch Act provides that the period of 180-day exclusivity is triggered by the earlier of a court decision finding the patent at issue invalid or not infringed or the commercial marketing of the product. Under certain circumstances, we may not be able to exploit our 180-day exclusivity period completely since it may be triggered prior to our being able to market the product.

For example, recent court decisions have interpreted the 180-day exclusivity period as starting from an initial ruling by a federal district court (instead of a final, unappealable ruling) regarding the validity or infringement of a patent. If we choose to bring a product to market prior to receiving a final ruling and an appellate court overturns the initial ruling, we could face significant infringement damages. These recent court decisions may cause us to take on patent risks that we were not exposed to prior to those decisions in order to benefit from the 180-day exclusivity period, or, conversely, we may choose not to take advantage of the 180-day exclusivity period rather than risk an adverse ruling in an appellate court. In addition to these issues, our patent challenges may be unsuccessful, which may result in a bar to the FDA granting market approval until the relevant patent expires. Another recent FDA ruling allows for joint 180-day exclusivity under certain circumstances. As a result, there may be certain circumstances in which we may share our exclusivity with one or more companies.

***If we elect to sell a generic product prior to the completion of all appellate level patent litigation, we could be subject to liabilities for damages if a lower court judgment upon which we are relying is reversed.***

At times we seek approval to market generic products before the expiration of patents for those products, based upon our belief that such patents are invalid, unenforceable, or would not be infringed by Teva's products. As a result, we often face significant patent litigation. Depending upon a complex analysis of a variety of legal and commercial factors, if we win a lower court decision in such patent litigation, we may, in certain circumstances, elect to market a generic product even though an appeal of the lower court decision is pending. Should we elect to proceed in this manner, we could face substantial patent liability damages were a higher court to overturn the trial court's decision.

***Our sales of Copaxone® could be adversely affected by competition.***

Copaxone®, is our leading innovative product, from which we derive substantial revenues and profits. To date, we and our marketing partners have been successful in our efforts to establish Copaxone® as a leading therapy for multiple sclerosis and have increased our global market share among the four currently available major therapies for multiple sclerosis. However, Copaxone® faces intense competition, including as a result of the recent entry of Serono SA's beta-interferon product, Rebif®, into the U.S. market and the role that Pfizer Inc. has recently assumed as a co-marketer with Serono of this product in the United States.

***We are subject to government regulation that increases our costs and could prevent us from marketing or selling our products.***

We are subject to extensive pharmaceutical industry regulations in Israel, the United States, England, Hungary, the Netherlands, Canada, France, Italy and other jurisdictions. We cannot predict the extent to which we may be affected by legislative and other regulatory developments concerning our products.

We are dependent on obtaining timely approvals before marketing most of our products. In the United States, any manufacturer failing to comply with FDA or other applicable regulatory agency requirements may be unable to obtain approvals for the introduction of new products and, even after approval, initial product shipments may be delayed. The FDA also has the authority to revoke drug approvals previously granted and remove from the market previously approved drug products containing ingredients no longer approved by the FDA. Our major facilities, both in the United States and outside the United States, and products are periodically inspected by the FDA, which has extensive enforcement

powers over the activities of pharmaceutical manufacturers, including the power to seize, force to recall and prohibit the sale or import of non-complying products, and halt operations of and criminally prosecute non-complying manufacturers.

In Europe and Israel, the manufacture and sale of pharmaceutical products is regulated in a manner substantially similar to that in the United States. Legal requirements generally prohibit the handling, manufacture, marketing and importation of any pharmaceutical product unless it is properly registered in accordance with applicable law. The registration file relating to any particular product must contain medical data related to product efficacy and safety, including results of clinical testing and references to medical publications as well as detailed information regarding production methods and quality control. Health ministries are authorized to cancel the registration of a product if it is found to be harmful or ineffective or manufactured and marketed other than in accordance with registration conditions.

***We may not be able to successfully identify, consummate and integrate recent and future acquisitions.***

In the past, we have grown, in part, through a number of significant acquisitions. We plan to remain frequently engaged in various stages of evaluating or pursuing potential acquisitions and may in the future acquire other pharmaceutical and active pharmaceutical ingredients businesses and seek to integrate them into our own operations. The recent and future acquisitions of additional companies involve risks that could adversely affect our future revenues and operating results. For example:

- We may not be able to identify suitable acquisition candidates or to acquire companies on favorable terms.
- We compete with others to acquire companies. We believe that this competition will increase and may result in decreased availability or increased prices for suitable acquisition candidates.
- We may not be able to obtain the necessary financing, on favorable terms or at all, to finance any of our potential acquisitions.
- We may not be able to obtain the necessary regulatory approvals, including the approval of anti-competition regulatory bodies, in any countries in which we may seek to consummate potential acquisitions.
- We may ultimately fail to close an acquisition even if we announce that we plan to acquire a company.
- We may fail to integrate successfully our acquisitions in accordance with our business strategy.
- We may choose to acquire a company that is not profitable.
- Potential acquisitions may divert management's attention away from our primary product offerings, result in the loss of key customers and/or personnel and expose us to unanticipated liabilities.
- We may not be able to retain the skilled employees and experienced management that may be necessary to operate the businesses we may acquire and, if we cannot retain such personnel, we may not be able to locate or hire new skilled employees and experienced management to replace them.
- We may purchase a company that has contingent liabilities that include, among others, known or unknown patent or product liability claims.

***As a pharmaceutical company, we are susceptible to product liability claims that may not be covered by insurance.***

Our business inherently exposes us to potential product liability claims. From time to time, the pharmaceutical industry has experienced difficulty in obtaining product liability insurance coverage for certain products or coverage in the desired amounts or with the desired deductibles. As a result, we sell,

and may continue to sell, generic products that are not covered by insurance and may also be subject to product liability claims that are not covered by insurance or that exceed our policy limits.

Additionally, changes in the insurance markets subsequent to the September 11, 2001 terrorist attacks have made it more difficult for us to obtain certain types of coverage. We cannot assure you that we will be able to obtain the levels or types of insurance we would otherwise have obtained prior to these market changes or that the insurance coverage we do obtain will not contain large deductibles or fail to cover certain liabilities or that it will otherwise cover all potential losses.

***Reforms in the health care industry and the uncertainty associated with pharmaceutical pricing, reimbursement and related matters could adversely affect the marketing, pricing and demand for our products.***

Increasing expenditures for health care have been the subject of considerable public attention in Israel, North America and many European countries. Both private and governmental entities are seeking ways to reduce or contain health care costs. In many countries in which we currently operate, including Israel, pharmaceutical prices are subject to regulation. In the United States, numerous proposals that would effect changes in the United States health care system have been introduced or proposed in Congress and in some state legislatures. Similar activities are taking place throughout Europe. We cannot predict the nature of the measures that may be adopted or their impact on the marketing, pricing and demand for our products.

As a result of governmental budgetary constraints, the Israel Ministry of Health and the major Israeli health funds have sought to further reduce health care costs by, among other things, applying continuous pressure to reduce pharmaceutical prices and reducing inventory levels. The Israeli government has adopted regulations that permit the parallel importation of pharmaceutical products and set a maximum price on certain pharmaceutical products. Although such legislation is predominantly aimed at reducing prices of imported products, as opposed to locally manufactured products such as ours, it could have a secondary effect on us by increasing price competition within the Israeli pharmaceutical market.

***The success of our innovative products depends on the effectiveness of our patents and confidentiality agreements to defend our intellectual property rights.***

Our success with our innovative products depends, in part, on our ability to protect our current and future innovative products and to defend our intellectual property rights. If we fail to adequately protect our intellectual property, competitors may manufacture and market products similar to ours. We have been issued numerous patents covering our innovative products, 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. Any existing or future patents issued to or licensed by us may not provide us with any competitive advantages for our products or may even be challenged, invalidated or circumvented by competitors. In addition, such patent rights may not prevent our competitors from developing, using or commercializing products that are similar or functionally equivalent to our products.

We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation that we seek to protect, in part, by confidentiality agreements with licensees, suppliers, employees and consultants. It is possible that these agreements will be breached and we will not have adequate remedies for any such breach. 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, if patents are not issued with respect to products arising from research, we may not be able to maintain the confidentiality of information relating to such products.

***We have significant operations outside of the United States, including in Israel, that may be adversely affected by acts of terrorism or major hostilities.***

Significant portions of our operations are conducted outside of the United States. We may, therefore, be directly affected by economic, political and military conditions in the countries in which our businesses are located, as well as by currency exchange rate fluctuations and the exchange control regulations of such countries. Our executive offices and a substantial number of our manufacturing facilities are located in the State of Israel. Teva's Israeli operations are dependent upon materials imported from outside of Israel. We also export significant amounts of products from Israel. Accordingly, our operations could be materially and adversely affected by acts of terrorism or if major hostilities should occur in the Middle East or trade between Israel and its present trading partners should be curtailed, including as a result of acts of terrorism in the United States. Any such effects may not be covered by insurance.