

## RISK FACTORS

*Our business faces significant risks. You should carefully consider all of the information set forth in this Form 20-F 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 or results of operations could be materially adversely affected by any of these risks. This Form 20-F 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 due to the risks described below and elsewhere in this Form 20-F. See "Forward-Looking Statements" on page 3.*

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

Our future results of operations depend, to a significant degree, upon our ability to successfully commercialize additional generic and 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 and continue to comply with regulatory and safety standards and receive regulatory approvals; we may be forced to withdraw a product from the market if health or safety concerns arise with respect to such product. 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 we may not be able to successfully and profitably produce and market such products. Delays in any part of the process or our inability to obtain regulatory approval of our products (including the products filed by Andrx Corporation, IMPAX Laboratories Inc. and Biovail Corporation, for which we have exclusive marketing rights) could adversely affect our operating results by restricting or delaying 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, and particularly if we obtain the 180-day period of market exclusivity provided under the Hatch-Waxman Act, our sales, profit 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 or the launch of an authorized generic. 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, among other things, on our ability to continuously and timely introduce new products.

***Our generic pharmaceutical products face intense competition from brand-name companies that sell or license their own generic products or seek to delay the introduction of generic products.***

Brand-name pharmaceutical companies have taken aggressive steps to thwart competition from generic companies. In particular, brand-name companies continue to sell or license their products directly or through licensing arrangements or strategic alliances with generic pharmaceutical companies (so-called "authorized generics"). No significant regulatory approvals are required for a brand-name

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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 delay generic introduction and decrease the impact of generic competition, such as

- filing new patents on drugs whose original patent protection is about to expire;
- filing an increasing number of patents that are more complex and costly to challenge;
- filing suits for patent infringement that automatically delay FDA approval;
- developing patented controlled-release or other “next-generation” products, which often reduces demand for the generic version of the existing product for which we are seeking approval;
- 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.

These strategies may increase the costs and risks associated with our efforts to introduce generic products and may delay or prevent such introduction altogether.

***Changes in the regulatory environment may prevent us from utilizing the exclusivity periods that are important 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 extensive litigation in the United States. The FDA’s current interpretation of the Hatch-Waxman 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 Medicare Prescription Drug Act provides that the 180-day market exclusivity period provided under the Hatch-Waxman Act is only triggered by the commercial marketing of the product. However, the Medicare Act also contains forfeiture provisions which, if met, will deprive the first Paragraph IV filer of exclusivity. As a result, under certain circumstances, we may not be able to exploit our 180-day exclusivity period since it may be forfeited prior to our being able to market the product.

In addition, legal and administrative battles over triggering dates and shared exclusivities may also prevent us from fully utilizing the exclusivity periods.

***If we elect to sell a generic product prior to any court decision or prior to the completion of all appellate level patent litigation, we could be subject to liabilities for damages.***

At times we or our partners 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 our products. As a result, we face significant patent litigation. Depending upon a complex analysis of a variety of legal and commercial factors, we may, in certain circumstances, elect to market a generic product even though litigation is still pending. This could be before any court decision is rendered or while an appeal of a lower court decision is pending. To the extent we elect to proceed in this manner, we could face substantial liability for patent infringement if the final court decision is adverse to us. For example, in 2004 we launched oxycodone and generic versions of Neurontin® tablets and capsules despite the fact that litigation with the branded companies was still pending. Our ability to introduce new products may depend on our ability to successfully challenge patent rights held by branded companies.

***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 currently available major therapies for multiple sclerosis. However, Copaxone® faces intense competition from existing products, such as Avonex®, Betaseron® and Rebif®. We may also face competition from additional products in development. In addition, the exclusivity protections afforded us in the United States through orphan drug status for Copaxone® expired on December 20, 2003. If our patents on Copaxone® are successfully challenged, we may also face generic competition for this product.

***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 the United States, Canada, the European Union, and its member states including England, Hungary, The Netherlands, France and Italy, in Israel and in other jurisdictions. We cannot predict the extent to which we may be affected by legislative and other regulatory developments concerning our products. We are also subject to various environmental laws and regulations in the jurisdictions where we have operations.

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 our 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 similar in many respects 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.

Data exclusivity provisions exist in many countries worldwide, including in the European Union, where they were recently extended, although their application is not uniform. Similar provisions may be adopted by additional countries, including Israel, where legislation has been proposed. In general, these exclusivity provisions prevent the approval and/or submission of generic drug applications to the health authorities for a fixed period of time following the first approval of the brand name product in that country. As these exclusivity provisions operate independently of patent exclusivity, they may prevent the submission of generic drug applications for some products even after the patent protection has expired.

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

In the past, we have grown, in part, through a number of significant acquisitions, including our recent acquisition of Sicor Inc. We continue to be 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. Future acquisitions involve known and unknown risks that could adversely affect our future revenues and operating results. For example:

- We compete with others to acquire companies. We believe that this competition has intensified and may result in decreased availability or increased prices for suitable acquisition candidates.
- 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 consummate an acquisition even if we announce that we plan to acquire a company.
- We may fail to successfully integrate our acquisitions in accordance with our business strategy.
- Potential acquisitions may divert management's attention away from our primary product offerings, resulting 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, including potential claims relating to products that we previously sold or currently sell and that are not covered by insurance.***

Our business inherently exposes us to claims relating to the use of our products. We sell, and will continue to sell, pharmaceutical products for which product liability insurance coverage is not available, and accordingly, we may be subject to claims that are not covered by insurance as well as claims that exceed our policy limits. Additional products for which we currently have coverage may be excluded in the future. In addition, 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 coverage we desire. Because of the nature of these claims, we are generally not permitted under US GAAP to establish reserves in our accounts for such contingencies.

***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, including the enactment in December 2003 of expanded Medicare coverage for drugs. Similar activities are taking place throughout Europe and Israel. We cannot predict the nature of the measures that may be adopted or their impact on the marketing, pricing and demand for our products.

***The success of our innovative products depends on the effectiveness of our patents and other measures we take to protect 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 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 international operations, including in Israel, which may be adversely affected by acts of terrorism, major hostilities or adverse legislation or litigation.***

Significant portions of our operations are conducted outside of the United States, and we import a substantial number of products into the United States. We may, therefore, be directly affected and denied access to our customers by a closure of the borders of the United States for any reason or other economic, political and military conditions in the countries in which our businesses are located. We may also be affected by currency exchange rate fluctuations and the exchange control regulations of such countries or other political crisis or disturbances, which impede access to our suppliers.

Our executive offices and a substantial number of our manufacturing facilities are located in 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

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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.

We may be subject to legislation in Israel, primarily relating to the protection of patents and data exclusivity provisions, that would prevent us from exporting Israeli-manufactured products in a timely fashion. Additionally, the existence of third party patents in Israel, with the attendant risk of litigation, may cause Teva to move production outside of Israel or otherwise adversely affect our ability to export certain products from Israel. Although legislation addressing these problems has been proposed, we can not assure you that it will be enacted.

**ITEM 4: INFORMATION ON THE COMPANY**

Teva Pharmaceutical Industries Limited is a global pharmaceutical company producing drugs in all major treatment categories. Teva is one of the world's largest generic drug companies and has the leading position in the U.S. generic market. Teva has successfully utilized its production and research capabilities to establish a global pharmaceutical operation focused on supplying the growing demand for generic drugs and on opportunities for proprietary branded products for specific niche categories, with its leading branded drug being Copaxone® for multiple sclerosis. Teva's active pharmaceutical ingredients ("API") business provides both significant revenues and profits from sales to third party manufacturers and strategic benefits to Teva's own pharmaceutical production through its timely delivery of significant raw materials.

Teva's operations are conducted directly and through subsidiaries in Israel, Europe, North America and several other jurisdictions. During 2004, Teva generated approximately 64% of its sales in North America, 26% in Europe and 10% in the rest of the world, predominantly in Israel. For a breakdown of Teva's sales by business segment and by geographic market for the past three years, see "Item 5: Operating and Financial Review and Prospects - Results of Operations - Sales - General."

Teva was incorporated in Israel on February 13, 1944 and is the successor to a number of Israeli corporations, the oldest of which was established in 1901. Its executive offices are located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel, telephone number 972-3-926-7267.

**2004 Acquisitions.** Teva's significant growth during the past decade is in large part attributable to numerous acquisitions it has made in North America and Europe. In January 2004, Teva completed its acquisition of Sicor Inc., a generic pharmaceutical company based in California, with facilities in Mexico, Italy and Lithuania, for approximately \$3.46 billion in cash and Teva shares. This acquisition, Teva's largest acquisition to date, combined Teva's oral dose generic drugs franchise with Sicor's generic injectables business, with Sicor's API business complementing Teva's global API offerings. The Sicor acquisition further provided Teva with new capabilities for the development and production of biological products. Integration of Sicor's businesses into Teva's operations was substantially completed during 2004. In addition, in December 2004, Teva acquired Dorom S.r.l., one of the largest suppliers of generic pharmaceuticals to the Italian retail market, for approximately \$93 million in cash.

**Pharmaceutical Products****Generic Products**

Teva is one of the largest generic drug companies in the world. Generic drugs are the chemical and therapeutic equivalents of brand-name drugs, typically sold under their generic chemical names at prices below those of their brand-name equivalents. These drugs are required to meet similar governmental regulations as their brand-name equivalents and must receive regulatory approval prior to their sale in any given country. Generic drugs may be manufactured and marketed only if relevant patents on their brand-name equivalents (and any additional government-mandated market exclusivity periods) have expired, been challenged and invalidated, or otherwise validly circumvented.

Global generic pharmaceutical sales have been positively impacted in recent years by the increased awareness and acceptance among consumers, physicians and pharmacists that generic drugs are the equivalents of brand-name drugs. Among the factors contributing to this increased awareness are the passage of legislation permitting or encouraging substitution and the publication by regulatory authorities