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 the risks we face as described below and elsewhere. See "Forward-Looking Statements" on page 4.

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 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, 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. 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 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 to the generic market directly by acquiring or forming strategic alliances with generic pharmaceutical companies. No significant 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 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,

developing patented controlled-release products, changing product claims and product labeling, granting third parties the rights to sell "authorized generics," 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 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 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.

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 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 our products. As a result, we often 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 or while an appeal of a lower court decision is pending. Should we elect to proceed in this manner, we could face substantial patent liability damages if the final court decision is adverse to us. For example, we continue to market Moexipril HCl tablets (which we began shipping in May 2003) despite the fact that an appellate court has returned to the lower court for further proceedings a decision of non-infringement that had been in our favor.

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 from currently marketed interferon-based products such as Betaseron®, Avonex®, and Rebif®, as well as potential competition from products in development, such as Antegren®. In addition, the exclusivity protections afforded us in the United States through orphan drug status for Copaxone® expired on December 20, 2003. To the extent that our patents on Copaxone® are challenged and if any such challenges are successful, we may 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, England, Hungary, The Netherlands, Canada, France, Italy, Israel 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 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.

We may experience difficulties in integrating and operating Sicor's business with the existing Teva businesses.

Our recent acquisition of Sicor involves the integration of a company that has previously operated independently and constitutes the largest acquisition we have ever undertaken. The difficulties of combining Sicor's operations with ours include:

- the necessity of coordinating and consolidating geographically separated organizations, systems and facilities; and
- integrating the management and personnel of Sicor and Teva, maintaining employee morale and retaining key employees.

The process of integrating operations could cause an interruption of, or loss of momentum in, the activities of our businesses and the loss of key personnel. The diversion of management's attention and any delays or difficulties encountered in connection with the acquisition and the integration of Sicor's operations could have an adverse effect on our business, results of operations, financial conditions or prospects.

Achieving the anticipated benefits of the acquisition will depend in part upon whether we can integrate and operate the Sicor business in an efficient and effective manner. For example, prior to the

acquisition, we did not have significant relationships with U.S. hospitals, which are the principal customer base of Sicor, and we did not have biogenerics activities. We may not accomplish this integration process smoothly or successfully. If management is unable to successfully integrate Sicor's operations, the anticipated benefits of the acquisition may not be realized.

We may not achieve the revenue and cost synergies we expect for the combined Teva-Sicor company.

Our rationale for the acquisition was, in part, predicated on the projected ability of the combined company to realize certain revenue and cost synergies. Achieving these synergies is dependent upon a number of factors, some of which are beyond our control. These synergies may not be realized to the extent or within the time frame that we anticipate.

Sicor derives a large percentage of its sales from one product, propofol. If sales of propofol decrease below our expectations, we may not achieve the expected benefits from the acquisition.

Sicor markets the first generic formulation of propofol in the United States, which is currently the only generic propofol on the U.S. market. Accordingly, any factor adversely affecting sales of propofol, such as the introduction by other companies of additional generic equivalents of propofol or non-propofol injectable general anesthetics, may have a material adverse effect on us. In addition, the total market for propofol in the United States has fluctuated in recent years, and there can be no assurance that this market will not decline in the future.

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. 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. 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 will intensify 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 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.
- 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, including potential claims relating to products that we currently sell and that are not covered by insurance.

Our business inherently exposes us to potential product liability claims. From time to time, and particularly following changes in the insurance industry following the September 11, 2001 terrorist attacks, the pharmaceutical industry has experienced difficulty in obtaining product liability insurance coverage for certain products or coverage in the desired types and 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. Additional products for which we currently have coverage may be excluded in the future. In addition, because of the nature of these claims, we are generally not permitted 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. 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 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 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, 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, 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 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.

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 a 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 the 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 2003, Teva generated approximately 63% of its revenue in North America, 26% in Europe and 11% 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.

Recent Sicor Acquisition

In October 2003, Teva entered into an agreement to purchase Sicor Inc., a generic pharmaceutical company based in California, with facilities in Mexico, Italy and Lithuania. The transaction closed on January 22, 2004. The purchase price paid by Teva for Sicor amounted to approximately $3.46 billion in a combination of cash and Teva shares. The transaction was accounted for as a purchase and will begin to impact Teva's results commencing in the first quarter of 2004.

This acquisition combines Teva's oral dose generic drugs franchise with Sicor's generic injectables business. In addition, Sicor's API business should complement Teva's API offerings. The Sicor acquisition further provides Teva with new capabilities for the development and production of biological products.

We have provided additional details regarding Sicor in various sections throughout this report.

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.