TARO PHARMACEUTICAL INDUSTRIES LTD
Form 20-F
June 29, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

o **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2003

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number 0-22286

TARO PHARMACEUTICAL INDUSTRIES LTD.

(Exact name of Registrant as specified in its charter)

Israel

(Jurisdiction of incorporation or organization)

Italy House, Euro Park, Yakum 60972, Israel

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
None	None

Securities registered or to be registered pursuant to Section 12(g) of the Act:
Ordinary Shares, NIS 0.0001 nominal (par) value per share

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:
None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer s classes of capital or common stock as of the close of the period covered by the annual report:

28,969,218 Ordinary Shares, NIS 0.0001 nominal (par) value per share

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

x Yes o No

Indicate by check mark which financial statement item the registrant has elected to follow.

o Item 17 x Item 18

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INTRODUCTION

We develop, manufacture and market prescription and over-the-counter, or OTC, pharmaceutical products, as well as active pharmaceutical ingredients, or APIs, primarily in the United States, Canada and Israel. We were incorporated in 1959 under the laws of the State of Israel. In 1961, we completed the initial public offering of our ordinary shares in the United States. In October 2001, we sold 3,950,000 of our ordinary shares, and selling shareholders sold 1,800,000 of our ordinary shares, in a public offering. Our ordinary shares are currently traded on the Nasdaq National Market under the symbol TARO.

In July 2001, we completed a split of our ordinary shares by distributing a dividend of one ordinary share for every ordinary share then outstanding and one ordinary share for every ten founders shares then outstanding. All ordinary share and per share numbers contained in this annual report have been adjusted to give effect to this dividend.

Except for the historical information contained in this annual report, the statements contained herein are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition and results of operations. Actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including all the risks discussed in Item 3 Key Information-Risk Factors and elsewhere in this annual report.

We urge you to consider that statements which use the terms *believe, expect, plan, intend, estimate, anticipate, should, will, may* and similar expressions are intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. Except as required by applicable law, including the securities laws of the United States, we do not intend to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Our consolidated financial statements appearing in this annual report are prepared in U.S. dollars and in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. All references in this annual report to dollars, or $, are to U.S. dollars and all references in this annual report to NIS are to New Israeli Shekels. The published representative exchange rate between the NIS and the dollar for March 31, 2004 was NIS 4.53 per $1.00. The published representative exchange rate between the Canadian dollar and the dollar for March 31, 2004 was $1.31 Canadian dollar per $1.00.

As used in this annual report, the terms *we, us, our* and the *Company* mean Taro Pharmaceutical Industries Ltd. and its subsidiaries, unless otherwise indicated.

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PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. SELECTED FINANCIAL DATA

We have derived the following selected consolidated financial data as of December 31, 2003 and 2002 and for each of the years ended December 31, 2003, 2002 and 2001 from our consolidated financial statements set forth elsewhere in this annual report that have been prepared in accordance with U.S. GAAP. We have derived the consolidated selected financial data as of December 31, 2001, 2000 and 1999 and for each of the years ended December 31, 2000 and 1999 from our audited consolidated financial statements not included in this annual report. In July 2001, we completed a split of our ordinary shares, NIS 0.0001 nominal (par) value per share, by distributing as a dividend one ordinary share for every ordinary share then outstanding and one ordinary share for every ten founders shares then outstanding. All ordinary share and per share numbers contained in this annual report have been adjusted to give effect to this stock split.

You should read the selected consolidated financial data together with Item 5 - Operating and Financial Review and Prospects and our consolidated financial statements included elsewhere in this annual report.

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	Year Ended December 31,				
	2003	2002	2001	2000	1999
	(In thousands of U.S. dollars except per ordinary share data)				
Statement of Income Data:					
Sales	$315,458	$211,581	$149,230	$103,797	$83,785
Cost of sales	102,454	79,468	54,736	41,206	35,314
Gross profit	213,004	132,113	94,494	62,591	48,471
Operating expenses:					
Research and development, net	40,601	26,373	19,633	14,593	11,728
Selling, general and Administrative	97,718	52,481	42,086	31,902	25,933
Total operating expenses	138,319	78,854	61,719	46,495	37,661
Operating income	74,685	53,259	32,775	16,096	10,810
Financial expenses, net	1,722	162	2,594	3,855	3,869
Other income (loss), net	(7)	78	272	344	94
Income before taxes on income	72,956	53,175	30,453	12,585	7,035
Taxes on income	11,475	8,406	4,378	2,538	1,471
	61,481	44,769	26,075	10,047	5,564
Minority interest in earnings of a subsidiary	(326)	(214)	(81)	(20)	(25)
Net income	$ 61,155	$ 44,555	$ 25,994	$ 10,027	$ 5,539
Earnings per ordinary share:					
Basic	$ 2.12	$ 1.55	$ 1.11	$ 0.47	$ 0.27
Diluted	$ 2.06	$ 1.52	$ 0.99	$ 0.42	$ 0.25
Number of ordinary shares used in computing earnings per ordinary share:					
Basic	28,873	28,665	23,370	21,420	20,151
Diluted	29,674	29,408	26,302	23,864	21,525

	As of December 31,				
	2003	**2002**	**2001**	**2000**	**1999**
	(In thousands of U.S. dollars)				
Consolidated Balance Sheet Data:					
Working capital	$279,955	$198,871	$196,711	$ 43,588	$25,964
Property, plant and equipment, net	182,306	93,358	54,024	41,827	34,624
Total assets	616,523	379,845	307,762	120,446	90,957
Short-term debt, including current maturities	43,544	10,272	8,231	8,491	11,396
Long-term debt	156,937	47,127	49,285	38,250	23,328
Minority interest	1,711	1,159	776	168	148
Shareholders equity	347,400	269,137	218,364	50,214	40,552

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B. CAPITALIZATION AND INDEBTEDNESS

Not applicable.

C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

D. RISK FACTORS

Our business, operating results and financial condition could be seriously harmed due to any of the following risks, among others. If we do not successfully address the risks to which we are subject, we could experience a material adverse effect on our business, results of operations and financial condition and our share price may decline. We cannot assure you that we will successfully address any of these risks.

Risks Relating to Our Industry

The pharmaceutical industry in which we operate is intensely competitive. We are particularly subject to the risks of competition. For example, the competition we encounter may have a negative impact upon the prices we may charge for our products, the market share of our products and our revenues and profitability.

The pharmaceutical industry in which we operate is intensely competitive. The competition which we encounter has an effect on our product prices, market share, revenues and profitability. Depending upon how we respond to this competition, its effect may be materially adverse to us. We compete with:

the original manufacturers of the brand-name equivalents of our generic products;

other drug manufacturers (including brand-name companies that also manufacture generic drugs); and

manufacturers of new drugs that may compete with our generic drugs and proprietary products.

Most of the products that we sell are either generic drugs or drugs in respect of which patents have expired. None of these products benefits from patent protection and are therefore more subject to the risk of competition than patented products. In addition, because many of our competitors have substantially greater financial, production, research and development resources, substantially larger sales and marketing organizations, and substantially greater name recognition than we have, we are particularly subject to the risks inherent in competing with them. For example, many of our competitors may be able to develop products and processes competitive with, or superior to, our own. Furthermore, we may not be able to differentiate our products from those of our competitors, successfully develop or introduce new products that are less

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costly or offer better performance than those of our competitors or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors.

Brand-name companies frequently take actions to prevent or discourage the use of generic drug products such as ours.

Brand-name companies frequently take actions to prevent or discourage the use of generic equivalents to their products, including generic products that we manufacture or market. Because most of the products that we sell are generic versions of brand-name drugs, we are particularly subject to the risk that the manufacturers and sellers of the brand-name equivalents of our products may take the following actions, among others:

filing new patents on products whose original patent protection is about to expire;

developing patented controlled-release products or other product improvements;

developing and marketing branded products as over-the-counter products;

increasing marketing initiatives, regulatory activities and litigation relating to our products or proposed products; and

introducing authorized generics to the marketplace.

Generally, no additional regulatory approvals are required for brand-name manufacturers to sell directly or through a third party to the generic market. Brand-name products that are licensed to third parties and are marketed under their generic name at discounted prices are known as authorized generics . This facilitates the sale by brand-name manufacturers of generic equivalents of their brand-name products. Because many brand-name companies are substantially larger than we are and have substantially greater resources than we have, we are particularly subject to the risks of their undertaking to prevent or discourage the use of those of our products that compete with theirs. Moreover, the introduction of authorized generics may make competition in the generic market more intense. It may also reduce the likelihood that a generic company like ours that may obtain the first ANDA approval for a particular product, be the first-to-market and/or the only generic alternative offered to the market and thus diminish the economic benefit associated with this position.

New developments by others could make our products or technologies non-competitive or obsolete.

The markets in which we compete and intend to compete are undergoing, and are expected to continue to undergo, rapid and significant technological change. We expect competition to intensify as technological advances are made. New developments by others may render our products or technologies non-competitive or obsolete. For example, AstraZeneca Pharmaceuticals have filed New Drug Applications for a novel oral direct thrombin inhibitor, Exanta® (ximelagatran). If approved by regulatory authorities, the launch of Exanta® may have an adverse effect on our sales of

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Coumadin® in Israel and warfarin in the United States and Canada. A reduction in the sales and profitability of warfarin may have an adverse effect on the results of our operations and financial condition.

Our ability to market products successfully depends, in part, upon the acceptance of the products not only by consumers, but also by independent third parties.

Our ability to market generic or proprietary pharmaceutical products successfully depends, in part, on the acceptance of the products by independent third parties (including physicians, pharmacies, government formularies and other retailers) as well as patients. In addition, unanticipated side effects or unfavorable publicity concerning any of our products could have an adverse effect on our ability to achieve acceptance by prescribing physicians, managed care providers, pharmacies and other retailers, customers and patients.

Our ongoing profitability depends upon our ability to introduce new generic or innovative products on a timely basis.

Our ongoing profitability depends, to a significant extent, upon our ability to introduce, on a timely basis, new generic or innovative products for which we either are the first to market (or among the first to market) or can otherwise gain significant market share. Our ability to achieve any of these objectives is dependent upon, among other things, the timing of regulatory approval of these products and the number and timing of regulatory approvals of competing products. Inasmuch as this timing is not within our control, we may not be able to develop and introduce new generic and innovative products on a timely basis, if at all.

Our revenues and profits from individual generic pharmaceutical products are likely to decline as our competitors introduce their own generic equivalents.

Revenues and gross profit derived from generic pharmaceutical products tend to follow a pattern based on regulatory and competitive factors unique to the generic pharmaceutical industry. As the patents for a brand-name product and the related exclusivity periods expire, the first generic manufacturer to receive regulatory approval for a generic equivalent of the product is often able to capture a substantial share of the market. However, as other generic manufacturers receive regulatory approvals for competing products, or brand-name manufacturers introduce authorized generics , that market share and the price of that product will decline. For example, in May 2001, we began to market the first generic equivalent of Schering-Plough s Lotrisone® cream to be sold to the public in the United States. Competitors have introduced their own generic equivalents of Lotrisone® cream and additional competitors can be expected to enter the market. The introduction of additional generic equivalents or price reductions of existing generic products may have an adverse effect on revenues from our products, including our generic equivalent of Lotrisone® cream.

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

We are subject to extensive regulation by the United States, Canada, Israel and other jurisdictions. These jurisdictions regulate the approval, testing, manufacture, labeling, marketing and sale of pharmaceutical products. For example, approval by the United States Food and Drug Administration, or FDA, is generally required before any new drug or the generic equivalent to any previously approved drug may be marketed in the United States. The process for obtaining FDA and other approvals is lengthy, costly and subject to the risk, among others, that approval will not be obtained. In addition, the labeling claims and marketing statements that we can make are limited by regulations and, in most cases, by the labeling claims made in brand-name packaging.

In addition, because we market a controlled substance in the United States and other controlled substances in Canada and Israel, we must meet the requirements of the United States Controlled Substances Act and its equivalents in Israel and Canada, as well as the regulations promulgated thereunder in each country. These regulations include stringent requirements for manufacturing controls, importation, receipt and handling procedures and security to prevent diversion of, or unauthorized access to, the controlled substances in each stage of the production and distribution process.

Furthermore, most of the products that we manufacture and distribute are manufactured outside the United States and must be shipped into the United States. The FDA and the U.S. Drug Enforcement Administration, in conjunction with the U.S. Customs Service, can exercise greater legal authority over goods that we seek to import into the United States than they can over products that are manufactured in the United States.

Although we devote significant time, effort and expense to addressing the extensive government regulations applicable to our business and obtaining regulatory approvals, we remain subject to the risk of being unable to obtain necessary approvals on a timely basis, if at all. Delays in receiving regulatory approvals could adversely affect our ability to market our products.

Product approvals by the FDA and by comparable foreign regulatory authorities may be withdrawn if compliance with regulatory standards is not maintained or if problems relating to the products are experienced after initial approval. In addition, if we fail to comply with governmental regulations we may be subject to fines, unanticipated compliance expenditures, interruptions of our production and/or sale, prohibition of importation, seizures and recalls of our products, criminal prosecution and debarment of us and our employees from the generic drug approval process.

Reimbursement policies of third parties, cost containment measures and healthcare reform could adversely affect the demand for our products and limit our ability to sell our products.

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Our ability to market our products depends, in part, on reimbursement levels for them and related treatment established by healthcare providers (including government authorities), private health insurers and other organizations, including health maintenance organizations and managed care organizations. Reimbursement may not be available for some of our products and, even if granted, may not be maintained. Limits placed on reimbursement could make it more difficult for people to buy our products and reduce, or possibly eliminate, the demand for our products. In the event that governmental authorities enact additional legislation or adopt regulations which affect third party coverage and reimbursement, demand for our products may be reduced with a consequent adverse effect, which may be material, on our sales and profitability. In addition, the purchase of our products could be significantly influenced by the following factors, among others:

trends in managed healthcare in the United States;

developments in health maintenance organizations, managed care organizations and similar enterprises;

legislative proposals to reform healthcare and government insurance programs; and

price controls and reimbursement policies relating to new and expensive medicines.

These factors could result in lower prices and a reduced demand for our products.

We are susceptible to product liability claims that may not be covered by insurance and could require us to pay substantial sums.

We face the risk of loss resulting from, and adverse publicity associated with, product liability lawsuits, whether or not such claims are valid. We may not be able to avoid such claims. In addition, our product liability insurance may not be adequate to cover such claims and we may not be able to obtain adequate insurance coverage in the future at acceptable costs. A successful product liability claim that exceeds our policy limits could require us to pay substantial sums.

The manufacture and storage of pharmaceutical products are subject to inherent risk.

Because chemical ingredients are used in the manufacture of pharmaceutical products and due to the nature of the manufacturing process itself, there is a risk of incurring liability for damages caused by or during the storage or refinement of both the chemical ingredients and the finished pharmaceutical products. Although we have never incurred any material liability for damages of that nature, we may be subject to liability in the future. In addition, while we believe our insurance coverage is adequate, it is possible that a successful claim would exceed our coverage, requiring us to pay a substantial sum.

The manufacture and storage of pharmaceutical and chemical products are subject to environmental regulation and risk.

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Because of the chemical ingredients of pharmaceutical products and the nature of their manufacturing process, the pharmaceutical industry is subject to extensive environmental regulation and the risk of incurring liability for damages or the costs of remedying environmental problems. Although we have never incurred any such liability in any material amount, we may be subject to liability in the future. We may also be required to increase expenditures to remedy environmental problems and comply with applicable regulations.

If we fail to comply with environmental regulations to use, discharge or dispose of hazardous materials appropriately or otherwise to comply with the conditions attached to our operating licenses, the licenses could be revoked and we could be subject to criminal sanctions and substantial liability. We could also be required to suspend or modify our manufacturing operations.

Testing required for the regulatory approval of our products is sometimes conducted by independent third parties. Any failure by any of these third parties to perform this testing properly may have an adverse effect upon our ability to obtain regulatory approvals.

Our applications for the regulatory approval of our products incorporate the results of testing and other information that are sometimes provided by independent third parties (including, for example, manufacturers of raw materials, testing laboratories, contract research organizations or independent research facilities). The likelihood of the products being tested to receive regulatory approval is, to some extent, dependent upon the quality of the work performed by these third parties, the quality of the third parties facilities and the accuracy of the information provided by third parties. We have little or no control over any of these factors.

Risks Relating to Our Company

We derive most of our revenues and profits from a small group of product lines.

In 2003, 2002 and 2001, seven product lines accounted for 54%, 53% and 57% of our consolidated sales, respectively. In 2003, 2002 and 2001, one product line accounted for approximately 11%, 16% and 19% of our consolidated sales, respectively. A significant decline in revenues or profitability of any one of these product lines may adversely affect the results of our operations and financial condition.

In 2003, three U.S. major wholesale customers accounted for approximately 46% of our consolidated sales. Any substantial decline in our sales to these customers, for any reason, would have an adverse effect on our revenues and profitability.

In 2003, AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc., collectively accounted for approximately 46% of our consolidated sales. We have no long-term agreement with these wholesalers and thus they may reduce or cease

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their purchases from us at any time in the future. Furthermore, any change in their buying pattern or changes in their policies and practices in relation to their working capital and inventory management may result in a reduction of purchases of our products. Any cessation or reduction of purchases from us would likely have a material adverse effect on the results of our operations and financial condition.

The nature of our business requires us to estimate future charges against wholesaler accounts receivable. If these estimates are not accurate, the results of our operations and financial condition could be adversely affected.

Sales to third parties, including government institutions, hospitals, hospital buying groups, pharmacy buying groups, pharmacy chains and others generally are made through wholesalers. We sell our goods to wholesalers and the wholesalers sell to third parties at times and in quantities needed by the third parties. Typically, we have a contract price with a third party that may be different from the price at which we sold to the wholesaler. At the time the third party purchases from the wholesaler, the wholesaler charges us back for any price differential. At the time of any individual sale to a wholesaler, we do not know under which contracts the wholesaler will sell goods to third parties. Therefore, at the time of each sale, we make a reasonable estimate of chargebacks and other credits associated with the sale and we reduce our revenue accounts accordingly. From time to time, the transactions reported by a wholesaler are different from our estimates. Actual transactions that differ materially from our estimates may result in a reduction in the value of our accounts receivable. The ultimate reconciliation of our accounts with those of the wholesalers may delay the collection of our accounts receivable.

Our inventories are dated and may become obsolete.

Industry standards require that pharmaceutical products be made available to customers from existing stock levels rather than on a made-to-order basis. Therefore, in order to accommodate market demand adequately, we strive to maintain sufficiently high levels of inventories. The growth of our sales in the past few years has resulted in higher levels of inventory in anticipation of additional business for new products and from new customers, the exact timing of which cannot be accurately determined. However, anticipated growth in sales of any individual product or of all products may not materialize. In this circumstance, inventories prepared for these anticipated sales may become obsolete and have to be written off. These write-offs, if any, could have an adverse affect on the results of our operations and financial condition.

Our future success depends on our ability to develop, manufacture and sell new products.

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Our future success is largely dependent upon our ability to develop, manufacture and market new commercially viable pharmaceutical products and generic equivalents of proprietary pharmaceutical products whose patents and other exclusivity periods have expired. Delays in the development, manufacture and marketing of new products will negatively impact our results of operations. Each of the steps in the development, marketing and manufacture of our products involves significant time and expense. We are, therefore, subject to the risks, among others, that:

- any products presently under development, if and when fully developed and tested, will not perform in accordance with our expectations;
- any generic product under development will, when tested, not be bioequivalent to its brand-name counterpart;
- necessary regulatory approvals will not be obtained in a timely manner, if at all;
- any of these new products cannot be successfully and profitably produced and marketed; or
- brand name companies can launch their products, either themselves or through third parties, in the form of authorized generic products which can reduce sales, prices and profitability of our newly approved generic products.

If we are unable to obtain raw materials, our operations could be seriously impaired.

We currently obtain some raw materials for our products from either a single supplier or a limited number of suppliers. Although we have not experienced significant difficulty in obtaining raw materials to date, material supply interruptions may occur in the future and we may have to obtain substitute materials or products. While for some raw materials we do have long-term supply agreements, for most raw materials we do not have any long-term supply agreements and we are therefore subject to the risk that our suppliers of raw materials may not continue to supply us with raw materials on satisfactory terms or at all.

Furthermore, obtaining the regulatory approvals required for adding alternative suppliers of raw materials for finished products we manufacture may be a lengthy process. We strive to maintain adequate inventories of single source raw materials in order to ensure that any delays in receiving regulatory approvals will not have a material adverse effect upon our business. However, we may not be successful in doing so and as a consequence we may be unable to sell some products pending approval of one or more alternate sources of raw materials. Any significant interruption in our supply stream could have a material adverse effect on our operations.

We are increasing our efforts to develop new proprietary pharmaceutical products, but these efforts may not be commercially successful.

Our principal business in North America has traditionally been the development, manufacture and marketing of generic equivalents of pharmaceutical products first

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introduced by other companies. However, we have recently increased our efforts to develop new proprietary products, including T-2000 and T2001 (our patented non-sedating barbiturate compounds) and the Elixsure® line of products utilizing NonSpil (our patented spill-resistant liquid drug delivery system.)

Expanding our focus beyond generic products and broadening our pipeline to include proprietary product candidates may require additional internal expertise or external collaboration in areas in which we currently do not have substantial resources and personnel. We may have to enter into collaborative arrangements with others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue independently. We may not be able to acquire the necessary expertise or enter into collaborative agreements on acceptable terms, if at all, to develop and market proprietary product candidates.

In addition, although a newly developed product may be successfully manufactured in a laboratory setting, difficulties may be encountered in scaling up for manufacture in commercially-sized batches. For this reason and others, only a small minority of all new proprietary research and development programs ultimately results in commercially successful drugs. A program (including any program of ours) cannot be deemed successful until it actually produces a drug that is commercially marketed for a significant period of time.

In order to obtain regulatory approvals for the commercial sale of our proprietary product candidates, we are required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of the products. We have limited experience in conducting clinical trials in these new product areas.

A clinical trial may fail for a number of reasons, including:

- failure to enroll a sufficient number of patients meeting eligibility criteria;
- failure of the product candidate to demonstrate safety and efficacy;
- the development of serious (including life threatening) adverse events (including, for example, side effects caused by or connected with exposure to the product candidate); or
- the failure of clinical investigators, trial monitors and other consultants or trial subjects to comply with the trial plan or protocol.

Any failure of a clinical trial for a product in which we have invested significant time or other resources could have a material adverse effect on our results of operations and financial condition.

Even if launched commercially, our proprietary products may face competition from existing or new products of other companies. These other companies may have greater resources, market access, and consumer recognition than we have. Thus, even if launched commercially, there can be no assurance that our proprietary products will be successful or profitable. In addition, advertising and marketing expenses associated with

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the launch of a proprietary product may adversely affect the results of our operations and financial condition.

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

We plan to pursue additional acquisitions of product lines and/or companies and seek to integrate them into our operations. The recent and future acquisitions of additional product lines and companies involve risks that could adversely affect our future revenues and results of operations. For example:

- we may not be able to identify suitable acquisition targets or to acquire companies on favorable terms;
- we compete with other companies that may have stronger financial positions to acquire product lines and companies. We believe that this competition will increase and may result in decreased availability or increased prices for suitable acquisition targets;
- 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 antitrust regulatory bodies, in any of the countries in which we may seek to consummate potential acquisitions;
- we may ultimately fail to complete an acquisition after we announce that we plan to acquire a product line or a company;
- we may fail to integrate successfully our acquisitions in accordance with our business strategy;
- we may choose to acquire a business that is not profitable at the time of acquisition;
- potential acquisitions may require significant management resources and divert attention away from our daily operations, result in the loss of key customers and 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 and hire new skilled employees and experienced management to replace them; or
- we may purchase a company that has contingent liabilities that include, among others, known or unknown patent or product liability claims.

We depend on our ability to protect our intellectual property and proprietary rights, but we may not be able to maintain the confidentiality, or assure the protection, of these assets.

Our success depends, in large part, on our ability to protect our current and future technologies and products and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market

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products similar to ours. Numerous patents covering our technologies have been issued to us, and we 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. Some patent applications in the United States are maintained in secrecy until the patent is issued. Because the publication of discoveries tends to follow their actual discovery by many months, we may not be the first to invent, or file patent applications on any of our discoveries. Patents may not be issued with respect to any of our patent applications and existing or future patents issued to or licensed by us may not provide competitive advantages for our products. Patents that are issued may be challenged, invalidated or circumvented by our competitors. Furthermore, our 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, non-patented proprietary expertise and continuing technological innovation that we seek to protect, in part, by entering into confidentiality agreements with licensees, suppliers, employees and consultants. These agreements may be breached and there may not be adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Moreover, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors. 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 these products.

Third parties may claim that we infringe on their proprietary rights and may prevent us from manufacturing and selling certain of our products.

There has been substantial litigation in the pharmaceutical industry with respect to the manufacture, use and sale of new products. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may be required to commence or defend against charges relating to the infringement of patent or proprietary rights. Any such litigation could:

require us to incur substantial expense, even if we are insured or successful in the litigation;

require us to divert significant time and effort of our technical and management personnel;

result in the loss of our rights to develop or make certain products; and

require us to pay substantial monetary damages or royalties in order to license proprietary rights from third parties.

Although patent and intellectual property disputes within the pharmaceutical industry have often been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and could include the long-term payment of royalties. These arrangements may be investigated by U.S. regulatory agencies and, if improper, may be invalidated. Furthermore, the required licenses may not be made available to us on acceptable terms. Accordingly, an adverse determination in a

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judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing and selling some of our products or increase our costs to market these products.

From time to time, we seek to market products before the patents for them expire. In order to do so in the United States, we must challenge the patent under the procedures set forth in the Waxman-Hatch Act of 1984. To the extent that we engage in patent challenge procedures, we are involved and expect to be involved in patent litigation regarding the validity or infringement of the originator s patent. Patent challenges are complex, costly and can take a significant time to complete.

In addition, when seeking regulatory approval for some of our products, we are required to certify to regulatory authorities, including the FDA, that such products do not infringe upon third party patent rights. Filing a certification against a patent gives the patent holder the right to bring a patent infringement lawsuit against us. Any lawsuit would delay regulatory approval by the FDA until the earlier of the resolution of such claim or 30 months from the patent holder s receipt of notice of certification. A claim of infringement and the resulting delay could result in substantial expenses and even prevent us from manufacturing and selling certain of our products.

Our launch of a product prior to a final court decision or the expiration of a patent held by a third party may result in substantial damages to us. Depending upon the circumstances, a court may award the patent holder damages equal to three times their loss of income. If we are found to infringe a patent held by a third party and become subject to such treble damages, these damages could have a material adverse effect on the results of our operations and financial condition.

Volatility of the market price of our ordinary shares could adversely affect us and our shareholders.

The market price of our ordinary shares may be volatile, and could be subject to wide fluctuations, for the following reasons, among others:

actual or anticipated variations in our quarterly operating results or those of our competitors;

announcements by us or our competitors of new and enhanced products;

market conditions or trends in the pharmaceutical industry;

developments or disputes concerning proprietary rights;

introduction of technologies or product enhancements by others that reduce the need for our products;

changes in financial estimates by securities analysts;

general economic and political conditions;

departures of key personnel;

changes in the market valuations of our competitors;

regulatory considerations; and

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the other risk factors listed in this section.

Four of our directors, and members of their immediate families, currently control 49.5% of the voting power in our company.

Dr. Barrie Levitt, Aaron Levitt, Dr. Daniel Moros, Tal Levitt and members of their immediate families currently control, through their beneficial ownership of outstanding ordinary shares and founders shares, approximately 49.5% of the voting power in our company. Dr. Levitt and Mr. Levitt are brothers. Dr. Moros is their cousin and Ms. Levitt is Dr. Levitt s daughter. By reason of their shareholdings, the Levitt and Moros families should be able to control the outcome of most actions that require majority shareholder approval, including the election of directors, the appointment of management, the entering into of mergers, sales of substantially all of our assets and other extraordinary transactions. The company s board of directors has the authority, subject to the terms and limitations of our debt agreements, to issue additional shares, implement share repurchase programs, declare interim dividends and make other decisions about our shares. For information concerning a prospective change in the shareholdings of the persons referred to in this paragraph, please see Note (3) to the table set forth under the heading E. SHARE OWNERSHIP in ITEM 6 below.

50% of the voting power in our subsidiary Taro Pharmaceuticals U.S.A., Inc., or Taro U.S.A., is held by a corporation which is jointly controlled by the Chairman of our Board of Directors and by our President.

The share capital of Taro U.S.A. is divided into two classes. We own 96.9% of the shares that have economic rights and 50% of the shares that have voting rights in Taro U.S.A. Taro Development Corporation, or TDC, owns 3.1 % of the shares that have economic rights and 50% of the shares that have voting rights in Taro U.S.A. Dr. Levitt and Mr. Levitt are able to vote an aggregate of 54.7% of the outstanding voting shares of TDC and thereby control TDC. Although TDC has agreed to vote all of its shares in Taro U.S.A. for the election to its board of directors of such persons as we may designate, TDC may terminate the agreement upon one year written notice. In the event that TDC were to cease voting its shares in Taro U.S.A. for our designees or otherwise in accordance with our preference, TDC could prevent us from electing a majority of the board of directors of Taro U.S.A., effectively block actions that require approval of a majority of the voting power in Taro U.S.A. and potentially preclude us from consolidating Taro U.S.A. into our financial statements. Taro U.S.A. accounted for approximately 90% of our consolidated sales in 2003. For information concerning a prospective change in the ownership of TDC, please see Note (3) to the table set forth under the heading E. SHARE OWNERSHIP in ITEM 6 below.

No citizen or resident of the United States who acquired or acquires any of our ordinary shares at any time after October 21, 1999 is permitted to exercise more than 9.9% of the voting power in our company, with respect to such ordinary shares, regardless of how many shares the shareholder owns.

In order to reduce our risk of being classified as a Controlled Foreign Corporation under the United States Internal Revenue Code of 1986, as amended, or the Code, we amended our Articles of Association in 1999 to provide that no owner of any of our ordinary shares is entitled to any voting right of any nature whatsoever with respect

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to such ordinary shares if (a) the ownership or voting power of such ordinary shares was acquired, either directly or indirectly, by the owner after October 21, 1999 and (b) the ownership would result in our being classified as a Controlled Foreign Corporation. This provision has the practical effect of prohibiting each citizen or resident of the United States who acquired or acquires our ordinary shares after October 21, 1999 from exercising more than 9.9% of the voting power in our company, with respect to such ordinary shares, regardless of how many shares the shareholder owns. The provision may therefore discourage U.S. persons from seeking to acquire, or from accumulating, 15% or more of our ordinary shares (which, due to the voting power of the founders shares, would represent 10% or more of the voting power of our company).

We face risks related to foreign currency exchange rates.

Because some of our revenue, operating expenses, assets and liabilities are denominated in foreign currencies, we are subject to foreign exchange risks that could adversely affect our operations and reported results. To the extent that we incur expenses in one currency but earn revenue in another, any change in the values of those foreign currencies relative to the U.S. dollar could cause our profits to decrease or our products to be less competitive against those of our competitors. To the extent that our foreign currency and receivables denominated in a foreign currency are greater or less than our liabilities denominated in a foreign currency, we have foreign exchange exposure.

Our business requires us to move goods across international borders. Any events that interfere with, or increase the costs of, the transfer of goods across international borders could have a material adverse effect on our business.

We transport most of our goods across international borders, primarily those of the United States, Canada and Israel. Since the terrorist attacks that occurred in the United States on September 11, 2001, there has been more intense scrutiny of goods that are transported across international borders. As a result, we may face delays, and increases in costs due to such delays, in delivering goods to our customers. Any events that interfere with, or increase the costs of the transfer of goods across international borders could have a material adverse effect on our business.

Risks Relating to Our Location in Israel

Conditions in Israel affect our operations and may limit our ability to produce and sell our products.

We are incorporated under Israeli law and our principal offices and a significant component of our manufacturing and research and development facilities are located in Israel. Political, economic and military conditions in Israel directly affect our operations, and we could be adversely affected by hostilities involving Israel, the interruption or curtailment of trade between Israel and its trading partners or a significant downturn in the economic or financial condition of Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab

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neighbors and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel. Since October 2000, there has been a marked increase in hostilities between Israel and the Palestinians, which has continued with varying levels of severity and which has adversely affected the peace process and negatively influenced Israel s relationship with several Arab countries and international organizations. Furthermore, certain parties with whom we do business have declined to travel to Israel during this period, forcing us to make alternative arrangements where necessary, and the United States Department of State has issued an advisory regarding travel to Israel, impeding the ability of travelers to attain travel insurance. As a result of the State Department s advisory, the FDA has at various times curtailed or prohibited its inspectors from traveling to Israel to inspect the facilities of Israeli companies, which, should it occur with respect to our company, could result in the FDA withholding approval for new products we intend to produce at those facilities. Also, although it has not yet occurred, the political and security situation in Israel may result in certain parties with whom we have contracts claiming that they are not obligated to perform their commitments pursuant to force majeure provisions of those contracts.

In addition, since a significant component of our manufacturing and research and development facilities are located in Israel, we could experience disruption of our manufacturing and research and development due to terrorist attacks. If terrorist acts were to result in substantial damage to our facilities, our business activities would be disrupted since, with respect to some of our products, we would need to obtain prior FDA approval for a change in manufacturing site. Our business interruption insurance may not adequately compensate us for losses that may occur and any losses or damages incurred by us could have a material adverse effect on our business.

Some neighboring countries, as well as certain companies and organizations, continue to participate in a boycott of Israeli firms and others doing business with Israel or with Israeli companies. We are also precluded from marketing our products to certain of these countries due to U.S. and Israeli regulatory restrictions. Because none of our revenue is currently derived from sales to these countries, we believe that the boycott has not had a material adverse effect on our current operations. However, continuation or extension of the boycott and the implementation of additional restrictive laws, policies or practices directed towards Israel or Israeli businesses could have an adverse impact on the expansion of our business.

Finally, all male adult citizens and permanent residents of Israel under the age of 50 generally are obligated to perform up to 45 days of military reserve duty annually. Additionally, these residents are subject to being called to active duty at any time under emergency circumstances. Certain of our employees are currently obligated to perform annual reserve duty. Recently, there has been a significant call-up of military reservists, and it is possible that there will be additional call-ups in the future. While we believe that we have operated relatively efficiently given these requirements, both since we began operations and during the period of the increase in hostilities with the Palestinians since October 2000, we cannot predict the effect on our business operations if the conflict with the Palestinians continues to escalate or intensify. Our operations could be disrupted by

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the absence for a significant period of one or more of our executive officers or key employees or a significant number of our other employees due to obligatory military service requirement. Any disruption in our operations would harm our business.

We may be adversely affected if the rate of inflation in Israel exceeds the rate of devaluation of the New Israeli Shekel, or NIS, against the U.S. dollar.

A substantial portion of our expenses, primarily labor and occupancy expenses in Israel, is incurred in NIS. As a result, the cost of our operations in Israel, as measured in U.S. dollars, is subject to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the NIS in relation to the U.S. dollar or that the timing of any devaluation will lag behind inflation in Israel. If the U.S. dollar cost of our operations in Israel increases, our U.S. dollar-measured results of operations will be adversely affected.

Government price control policies can materially impede our ability to set prices for our products.

All pharmaceutical products sold in Israel are subject to price controls. Permitted price increases are enacted by the Israeli government as part of a formal review process. The inability to control the prices of our products may adversely affect our operations.

We currently benefit from government programs and tax benefits, both or either of which may be discontinued or reduced.

We currently receive grants and substantial tax benefits under Government of Israel programs, including the Approved Enterprise program and programs of the Office of the Chief Scientist of the State of Israel. In order to maintain our eligibility for these programs and benefits, we must continue to meet specified conditions, including making specified investments in fixed assets from our equity and paying royalties with respect to grants received. In addition, some of these programs restrict our ability to manufacture particular products or transfer particular technology outside of Israel. If we fail to comply with these conditions in the future, the benefits received could be canceled and we could be required to refund payments previously received under these programs or pay increased taxes. In recent years, the Government of Israel has reduced the benefits available under these programs, and these programs and tax benefits may be discontinued or curtailed in the future. If the Government of Israel ends these programs and tax benefits, our business, financial condition and results of operations could be materially adversely affected.

Provisions of Israeli law may delay, prevent or make a merger or acquisition of us difficult, which could prevent a change of control and depress the market price of our ordinary shares.

Provisions of Israeli corporate and tax law may have the effect of delaying, preventing or making a merger or acquisition of us more difficult. The Israeli Companies Law, or the Companies Law, generally requires that a merger be approved by a company s board of directors and by a shareholder vote at a shareholders meeting that

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has been called on at least 21 days advance notice. Any creditor of a merger party may seek a court order blocking a merger if there is a reasonable concern that the surviving company will not be able to satisfy all of the obligations of any party to the merger. Moreover, a merger may not be completed until at least 70 days have passed from the time that the merger proposal has been filed with the Israeli Registrar of Companies.

Other potential means of acquiring a public Israeli company such as ours might involve additional obstacles. In addition, a body of case law has not yet developed with respect to the Companies Law. Until this happens, uncertainties will exist regarding its interpretation.

Finally, Israeli tax law treats some acquisitions, such as stock-for-stock exchanges between an Israeli company and a foreign company, less favorably than do U.S. tax laws. The provisions of Israeli corporate and tax law and the uncertainties surrounding such laws may have the effect of delaying, preventing or making a merger or acquisition of us more difficult. This could prevent a change of control of us and depress the market price of our ordinary shares which otherwise might rise as a result of such a change of control.

It may be difficult to effect service of process and enforce judgments against directors, officers and experts named in this annual report.

We are incorporated in Israel. A majority of our executive officers and directors and some of the experts named in this annual report are nonresidents of the United States and a substantial portion of our assets and the assets of such persons are located outside the United States. Therefore, it may be difficult to enforce a judgment obtained in the United States against us or any of those persons or to effect service of process upon those persons. It may also be difficult to enforce civil liabilities under U.S. federal securities laws in original actions instituted in Israel.

Risks Relating to Our Location in Canada

Government price control policies can materially impede our ability to set prices for our products.

The Canadian Government Patented Medicine Prices Review Board, or PMPRB, monitors and controls prices of patented drug products marketed in Canada by persons holding, or licensed under, one or more patents. The PMPRB will approve an introductory price (based on a comparative analysis) and will require that the price not be increased each year thereafter by more than the annual increase of the Canadian Consumer Price Index. Consequently, the existence of one or more patents relating to a drug product, while providing some level of proprietary protection for the product, also triggers a governmental price control regime that significantly affects the Canadian pharmaceutical industry s ability to set pricing. The inability to control the prices of our products may adversely affect our operations.

Sales of our products in Canada depend, in part, upon their being eligible for reimbursement from drug benefit formularies.

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In each province of Canada there is a drug benefit formulary. A formulary lists the drugs for which a provincial government will reimburse qualifying pers