TARO PHARMACEUTICAL INDUSTRIES LTD
Form 20-F
July 02, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

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

OR

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended March 31, 2013

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

OR

¨ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES**

EXCHANGE ACT OF 1934

Date of event requiring this shell company report _____

Commission file number 001-35463

TARO PHARMACEUTICAL INDUSTRIES LTD.

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant s name into English)

Israel

(Jurisdiction of incorporation or organization)

14 Hakitor Street, Haifa Bay 26110, Israel

(Address of principal executive offices)

Michael Kalb

Interim Chief Financial Officer

Taro Pharmaceutical Industries Ltd.

c/o Taro Pharmaceuticals U.S.A., Inc.

3 Skyline Drive

Hawthorne, NY 10532

Tel: 914-345-9000

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Email: Michael.Kalb@taro.com

(Name, telephone, email and/or facsimile number and address of Company contact person)

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

None

(Title of Class)

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:

44,768,087 Ordinary Shares, NIS 0.0001 nominal (par) value per share, and 2,600 Founders Shares NIS 0.00001

nominal (par) value per share were issued and outstanding as of March 31, 2013

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ¨ Yes þ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ¨ Yes þ No

Note checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those sections.

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. þ Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). þ Yes ¨ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

¨ Large Accelerated Filer þ Accelerated Filer ¨ Non-Accelerated Filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP þ International Financial Reporting Standards as issued by the International Accounting Standards Board ¨ Other ¨

If Other has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ¨ Item 17 ¨ Item 18

If this is an Annual Report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ¨ Yes þ No

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INTRODUCTION

We, among other business activities, develop, manufacture and market prescription and over-the-counter (OTC) pharmaceutical products, primarily in the United States (the U.S.), Canada and Israel. We also develop and manufacture active pharmaceutical ingredients (APIs), primarily for use in our finished dosage form products. 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. As of March 22, 2012, our ordinary shares are traded on the New York Stock Exchange (the NYSE), under the symbol TARO.

As used in this Annual Report on Form 20-F for the year ended March 31, 2013 (the 2013 Annual Report), the terms we, us, our, Taro and th Company mean Taro Pharmaceutical Industries Ltd. (Taro Israel) and its subsidiaries, unless otherwise indicated.

During 2012, our Board of Directors (the Board) approved a change in our fiscal year end from December 31 to March 31. The new fiscal year end was effectuated to align our fiscal reporting period and our annual budget planning with that of our major shareholder, Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) (Sun Pharma).

This 2013 Annual Report is being filed in respect of the year ended March 31, 2013, and contains the audited consolidated financial statements for the year then ended. To disclose information as of the latest practicable date and to provide material information to shareholders, this 2013 Annual Report discloses events and other information occurring after the fiscal year ended March 31, 2013.

FORWARD-LOOKING STATEMENTS

Except for the historical information contained in this 2013 Annual Report, the statements contained herein, in particular with respect to our business, financial condition and results of operations, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934. 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 3D 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, hope* 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.

PRESENTATION OF FINANCIAL INFORMATION

Our consolidated financial statements appearing in this 2013 Annual Report are reported in United States dollars in thousands, unless otherwise indicated, and are prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP). Totals presented in this 2013 Annual Report may not total correctly due to rounding of numbers.

All references in this 2013 Annual Report to dollars, or $, are to United States dollars and all references in this Annual Report to NIS are to New Israeli Shekels. The published [(1)] representative exchange rate between the NIS and the dollar for March 31, 2013 was NIS 3.65 per $1.00. The published [(2)] representative exchange rate between the Canadian dollar and the dollar for March 31, 2013 was $1.02 Canadian dollar per $1.00. No representation is made that the NIS amounts or Canadian dollar amounts could have been, or could be, converted into dollars at rates specified herein or any other rate.

(1) As published by The Bank of Israel.
(2) As published by The Bank of Canada.

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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 for the year ended March 31, 2013, the three months ended March 31, 2012, and the years ended December 31, 2011 and 2010 and as of March 31, 2013 and March 31, 2012, from our audited consolidated financial statements set forth elsewhere in this 2013 Annual Report that have been prepared in accordance with U.S. GAAP. We have derived the consolidated selected financial data for each of the years ended December 31, 2009 and 2008 and as of December 31, 2011, 2010, 2009 and 2008 from our audited consolidated financial statements not included in this annual report. You should read the selected consolidated financial data together with *Item 5 Operating and Financial Review and Prospects* and our consolidated financial statements, related notes and other financial information included elsewhere in this 2013 Annual Report. In 2012, we changed our fiscal year end from December 31 to March 31.

	Year Ended March 31, 2013	Three months Ended March 31, 2012	Year Ended December 31, 2011	2010	2009	2008
	U.S. dollars and shares in thousands (except per share data)					
Consolidated Statements of Operations Data:						
Sales, net	$ 670,954	$ 145,141	$ 505,668	$ 392,535	$ 355,936	$ 327,351
Cost of sales	176,128	45,971	176,143	159,158	147,091	139,510
Gross profit	494,826	99,170	329,525	233,377	208,845	187,841
Operating expenses:						
Research and development, net	46,508	9,847	30,867	36,393	33,303	33,681
Selling, marketing, general and administrative	86,438	23,101	93,918	107,902	100,344	97,125
Settlements and loss contingencies	33,300					
Total operating expenses	166,246	32,948	124,785	144,295	133,647	130,806
Operating income	328,580	66,222	204,740	89,082	75,198	57,035
Financial (income) expenses, net	(3,931)	1,000	(3,697)	11,840	13,575	(1,754)
Other gain (loss), net	3,352	(94)	609	755	548	469
Income before income taxes	335,863	65,128	209,046	77,997	62,171	59,258
Tax expense (benefit)	67,799	17,791	24,551	10,477	(69,657)	13,541
Income from continuing operations	268,064	47,337	184,495	67,520	131,828	45,717
Net (loss) income from discontinued operations	(1,194)	66	(1,217)	(2,969)	(15,077)	(15,196)

Net income	266,870	47,403	183,278	64,551	116,751	30,521
Net income attributable to non-controlling interest	664	151	598	473	2,728	
Net income attributable to Taro	$ 266,206	$ 47,252	$ 182,680	$ 64,078	$ 114,023	$ 30,521
Net income from continuing operations attributable to Taro	$ 267,400	$ 47,186	$ 183,897	$ 67,047	$ 129,100	$ 45,717
Net (loss) income from discontinued operations attributable to Taro	(1,194)	66	(1,217)	(2,969)	(15,077)	(15,196)
Net income attributable to Taro	$ 266,206	$ 47,252	$ 182,680	$ 64,078	$ 114,023	$ 30,521
Net income per ordinary share from continuing operations attributable to Taro:						
Basic	$ 5.99	$ 1.06	$ 4.14	$ 1.66	$ 3.29	$ 1.17
Diluted	$ 5.98	$ 1.06	$ 4.14	$ 1.60	$ 3.18	$ 1.14
Net (loss) gain per ordinary share from discontinued operations attributable to Taro:						
Basic	$ (0.03)	$ *	$ (0.03)	$ (0.07)	$ (0.38)	$ (0.39)
Diluted	$ (0.03)	$ *	$ (0.03)	$ (0.07)	$ (0.37)	$ (0.38)
Net income per ordinary share attributable to Taro:						
Basic	$ 5.96	$ 1.06	$ 4.11	$ 1.59	$ 2.91	$ 0.78
Diluted	$ 5.95	$ 1.06	$ 4.11	$ 1.53	$ 2.81	$ 0.76
Weighted-average number of ordinary shares used to compute net income per share:						
Basic	44,678	44,476	44,406	40,272	39,232	39,200
Diluted	44,715	44,589	44,491	41,850	40,568	40,423

* Amount is less than $0.01

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	As of March 31,		As of December 31,			
	2013	2012	2011	2010	2009	2008
	(In thousands of U.S. dollars)					
Consolidated Balance Sheet Data:						
Working capital (deficiency)	$ 717,240	$ 454,762	$ 391,048	$ 165,851	$ 59,095	$ (12,773)
Property, plant and equipment, net	145,265	150,750	152,532	163,596	176,168	186,543
Total assets	1,106,636	856,424	795,845	556,442	575,889	473,098
Short-term debt, including current maturities of long-term debt	11,330	10,957	17,073	28,195	125,367	130,004
Long-term debt, net of current maturities	17,269	27,949	27,614	31,225	38,380	58,019
Shareholders equity	890,961	622,958	571,063	384,513	295,696	164,217

Dividends

We have never paid cash dividends and we do not anticipate paying any cash dividends in the foreseeable future. Our dividend policy is set forth below in *Item 8.A Consolidated Statements and Other Financial Information*.

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 may be seriously harmed due to any of the following risks, among others. If we do not successfully address the risks facing us, we may experience a material adverse change in 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 charge for our products, the market share of our products and our revenue 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, revenue and profitability. Depending upon how we respond to this competition, it may have a material adverse effect on us. We compete with:

- generic manufacturers of our brand-name drugs;
- the original manufacturers of the brand-name equivalents of our generic products;
- other drug manufacturers (including brand-name companies that also manufacture generic drugs);
- other generic drug manufacturers; 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 for which related patents have expired. Most of these products do not benefit from patent protection and are therefore subject to an increased risk of competition. In addition, because many of our competitors have substantially greater financial, production and 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 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.

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Other pharmaceutical companies frequently take actions to prevent or discourage the use of generic drug products such as ours.

Other pharmaceutical companies have increasingly taken actions, including the use of state and federal legislative and regulatory mechanisms, to prevent, delay or discourage the use of generic equivalents to their products, including generic products that we manufacture or market. If these efforts to delay or prevent generic competition are successful, our ability to sell our generic versions of products may be limited or prevented. This could have a material adverse effect on our future results of operations. These efforts have included, among others:

- filing new patents or extensions of existing patents on products whose original patent protection is about to expire, which could extend patent protection for the product and delay launch of generic equivalents;
- developing patented controlled-release products or other product improvements;
- developing and marketing branded products as OTC products;
- pursuing pediatric exclusivity for brand-name products;
- submitting citizen petitions to request that the Commissioner of the U.S. Food and Drug Administration (FDA) take administrative action with respect to an abbreviated new drug application (ANDA) approval;
- attaching special patent extension amendments to unrelated federal legislation;
- engaging in state-by-state initiatives to enact legislation that restricts the substitution of some brand-name drugs with generic drugs;
- making arrangements with managed care companies and insurers to reduce the economic incentives to purchase generic pharmaceuticals;
- introducing authorized generics or their own generic equivalents to the marketplace; and
- setting the price of brand-name drugs at or below the price of generic equivalents.

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 names at discounted prices are known as authorized generics. Such licensing facilitates the sale of generic equivalents of a company s own 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 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 that obtains the first ANDA approval for a particular product will be the first to market and/or the only generic alternative offered to the market and thus may diminish the economic benefit associated with this position.

We may experience declines in the sales volume and prices of our products as the result of the continuing trend of consolidation of certain customer groups, such as the wholesale drug distribution and retail pharmacy industries, as well as the emergence of large buying groups. The result of such developments could have a material adverse effect on our business, financial position and results of operations, and could cause the market value of our ordinary shares to decline.

We make a significant portion of our sales to a relatively small number of wholesalers, retail drug chains, food chains and mass merchandisers. If demand decreases significantly, our profitability could be negatively impacted. Also, these customers constitute an essential part of the distribution chain for generic pharmaceutical products and continue to undergo significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and consequently increasing product pricing pressures facing us. In addition, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions, potentially enables those groups to negotiate price discounts on our products. The result of these developments may have a material adverse effect on our business, financial position and results of operations, and could cause the market value of our ordinary shares to decline.

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

The markets in which we compete and intend to compete continue to undergo rapid and significant technological change. Our competitors may succeed in developing products and technologies that are more effective or less costly than any that we are developing, or that would render our products obsolete and non-competitive.

We anticipate that we will face increased competition in the future as new companies enter the market and novel or advanced technologies emerge. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Many of our competitors have significantly greater research and development, financial, sales and marketing, manufacturing and other resources than we have. As a result, they may be able to devote greater resources to the development, manufacture, marketing or sale of their products, initiate or withstand substantial price competition, or more readily take advantage of acquisitions or other opportunities.

Our ability to market products successfully depends, in part, upon the acceptance of our 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, managed care providers, insurance companies and retailers), as well as patients. In addition, unanticipated side effects or unfavorable publicity concerning any of our products, or any brand-name product of which our generic product is the equivalent, 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 future profitability depends upon our ability to continue monitoring our inventory levels in the distribution channel.

Our future profitability depends, in part, upon our ability to continue monitoring our inventory levels in the distribution channel. We obtain reports of the amount of our products held in inventory by our wholesaler customers. We use these reports as part of our process for monitoring inventory levels in our distribution channel and our exposure to product returns. If we lose access to these reports, we may not be able to adequately monitor our inventory levels in the distribution channel. The loss of our visibility into the distribution channel could cause inventory levels to build, exceeding market demand and resulting in our incurring significant and unanticipated expenditures to reimburse these wholesaler customers for product returns, which could materially affect our profitability and cash flows in an adverse manner.

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

Our future 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.

To the extent that we succeed in being the first-to-market generic version of a significant product, and particularly if we obtain the 180-day period of market exclusivity for the U.S. market provided under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), our sales, profits and profitability can be substantially increased in the period following the introduction of such product and prior to a competitor s introduction of an equivalent product. However, after the end of the 180-day exclusivity period, these sales, along with the profits therefrom, may diminish precipitously.

Our revenue and profits from individual generic pharmaceutical products typically decline as our competitors introduce their own generic equivalents.

Revenue 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

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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 typically decline. Our overall profitability depends on, among other things, our ability to continuously, and on a timely basis, introduce new products.

Risks Relating to Regulatory Matters

We are subject to extensive government regulation that increases our costs and could delay or 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 FDA is generally required before any new drug or the generic equivalent to any previously approved drug may be marketed in the United States. In order to receive approval from the FDA for each new drug product we wish to market, we must demonstrate, through rigorous clinical trials, that the new drug product is safe and effective for its intended use and that our manufacturing process for that product candidate complies with current Good Manufacturing Practices (cGMP). We cannot provide an assurance that the FDA will, in a timely manner, or ever, approve our applications for new drug products. The FDA may require substantial additional clinical testing or find that our drug product does not satisfy the standards for approval. In addition, in order to obtain approval for our product candidates that are generic versions of brand-name drugs, we must demonstrate to the FDA that each generic product candidate is bioequivalent to a drug previously approved by the FDA through the new drug approval process, known as an innovator, or brand-name reference drug. Bioequivalency may be demonstrated by comparing the generic product to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. If the FDA determines that an ANDA for a generic drug product is not adequate to support approval, it could deny our application or request additional information, including clinical trials, which could delay approval of the product and impair our ability to compete with other versions of the generic drug product.

If our product candidates receive FDA approval, the labeling claims and marketing statements that we can make for our new generic products are limited by statutes and regulations and, with respect to our generic drugs, by the labeling claims made in the brand-name product s packaging. In addition, if the FDA and/or a foreign regulatory authority approves any of our products, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive and ongoing regulatory requirements. As a manufacturer of pharmaceutical products distributed in the United States, we must also comply with cGMPs, which include requirements related to production processes, quality control and assurance and recordkeeping. Products that we manufacture and distribute in foreign jurisdictions may be regulated under comparable laws and regulations in those jurisdictions. The facilities of Taro Pharmaceuticals U.S.A., Inc. (Taro U.S.A.), our U.S. subsidiary, our manufacturing facilities and procedures and those of our suppliers are subject to periodic inspection by the FDA and foreign regulatory agencies. Any material deviations from cGMPs or other applicable standards identified during such inspections may result in enforcement actions, including delaying or preventing new product approvals, a delay or suspension in manufacturing operations, consent decrees or civil or criminal penalties. Further, discovery of previously unknown problems with a product or manufacturer may result in restrictions or sanctions with respect to the product, including withdrawal of the product from the market.

In addition, because we market a controlled substance in the United States and other controlled substances in Israel, we must meet the requirements of the United States Controlled Substances Act and its equivalents in Israel, 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. The United States Drug Enforcement Administration (DEA) and comparable regulatory authorities in Israel and Canada may periodically inspect our facilities for compliance with the United States Controlled Substances Act and its equivalents in Israel and Canada. Any failure to comply with these laws and regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal, of our DEA registration (or Israeli or Canadian equivalent), injunctions, or civil or criminal penalties.

Furthermore, all of the products that we manufacture and most of the products we distribute are manufactured outside the United States and must be shipped into the United States. The FDA and the DEA, in conjunction with the United States 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.

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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 sales, prohibition of importation, seizures and recalls of our products, criminal prosecution and debarment of us and our employees from the generic drug approval process.

Regulatory authorities may require New Drug Applications for products marketed under the Drug Efficacy Study Implementation Review and Compliance Policy.

Certain drug products were considered safe by the FDA as part of the Drug Efficacy Study Implementation (DESI) Review and Compliance Policy Guide Chapter 4, Subchapter 440 of 1968. These products have been marketed for many years and, while considered to be safe for their indicated use, lack data supporting effectiveness. Therefore, the FDA may at any time, or from time to time, review a product on the DESI list to determine if the product requires the submission of a New Drug Application (NDA), for the continued marketing of the product in the United States. The filing of an NDA may be expensive, time consuming and require more resources than those available to the Company to support the research for the NDA, thus requiring us to withdraw such DESI products, which we may market from time to time, from the market or to cease marketing them.

Changes in regulatory environment may prevent us from utilizing the exclusivity periods that are important for the success of some of our generic products.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the Medicare Act) provides that the 180-day market exclusivity period provided under the Hatch-Waxman Act is only triggered by commercial marketing of the product. However, the Medicare Act also contains forfeiture provisions which would deprive the first Paragraph IV filer (as defined below) of exclusivity if certain conditions are met. Accordingly, in situations where we are the first Paragraph IV filer, we may face the risk of forfeiture and therefore may not be able to exploit a given exclusivity period for specific products.

Under the terms of the Hatch-Waxman Act, a generic applicant must make certain certifications with respect to the patent status of the drug for which it is seeking approval. In the event that such applicant plans to challenge the validity or enforceability of an existing listed patent or asserts that the proposed product does not infringe an existing listed patent, it files a so-called Paragraph IV certification. The Hatch-Waxman Act provides for a potential 180-day period of generic exclusivity for the first company to submit an ANDA with a Paragraph IV certification and also lawfully maintains such certification. Such exclusivity prevents the approval of a subsequently submitted ANDA containing a Paragraph IV certification. The Medicare Act modified certain provisions of the Hatch-Waxman Act. Under the Medicare Act, final ANDA approval for a product subject to Paragraph IV patent litigation may be obtained upon the earlier of a favorable district court decision or 30 months from notification to the patent holder of the Paragraph IV filing. Exclusivity rights for the first Paragraph IV filer may be forfeited pursuant to the Medicare Act if the product is not marketed within 75 days of the final court decision, if tentative approval or final approval is not timely granted, and under other specified circumstances. Some of the changes made by the Medicare Act apply to ANDAs where the first certification was filed after the enactment of the Medicare Act; previously filed ANDAs generally continue to be governed by the previous law.

Pharmaceutical companies are required by international law to comply with adverse event reporting requirements.

Our failure to meet these reporting requirements in any jurisdiction could result in actions by regulatory authorities in that and/or other jurisdictions, including any of the following: warning letters, public announcements, restriction or suspension of marketing authorizations, revocation of marketing authorizations, fines or a combination of any of these actions.

Health care reform may have an impact on all segments of the health care industry.

On March 23, 2010, the U.S. government enacted the Patient Protection and Affordable Care Act (PPACA). A companion bill, the Health Care Education Affordability Reconciliation Act of 2010, which was enacted by the U.S. government on March 30, 2010, contains amendments to the PPACA that reconcile the Senate and House versions of the legislation. Together, these bills (the Acts) represent the most comprehensive overhaul ever enacted of both the public and private health care systems in the U.S.A.

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The Acts impose on manufacturers a variety of additional rebates, discounts, fees, taxes and reporting and regulatory requirements. In December 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) No. 2010-27, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers (a consensus of the FASB Emerging Issues Task Force).* This standard addresses how fees mandated by the Acts should be recognized and classified in the income statements of pharmaceutical manufacturers. Under the proposal, the annual fee would be recognized as a liability for the total amount and a corresponding deferred cost over the calendar year and presented as an operating expense. This ASU is effective for calendar years beginning after December 31, 2010. The adoption of ASU 2010-27 did not impact our financial statements during fiscal year ended March 31, 2013 as there were nominal fees charged and we anticipate the fees to be nominal in fiscal year ended March 31, 2014.

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.

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.

The Acts are a sweeping measure intended to expand healthcare coverage in the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Among other things, the Acts contain provisions that will change payment levels for pharmaceuticals under Medicaid and increase pharmaceutical rebates under the Medicaid Drug Rebate Program. Effective October 1, 2010, the law changed the formula for calculating federal upper limits (FUL), which are a type of cap on the amount a state Medicaid program can reimburse pharmacies for multiple source drugs (drugs for which there are at least three equivalent versions on the market). When these provisions are implemented, the FUL will be calculated based on the weighted-average of the average manufacturer prices (AMPs) of the equivalent drugs on the market. In addition, the law changed the preexisting definition of AMP so that it is based only on direct sales to retail community pharmacies and sales to wholesalers who sell to retail community pharmacies. The Centers for Medicare & Medicaid Services (CMS) has not yet begun to implement the new FUL provisions and has not issued final regulations to implement the new statutory definition of AMP. We do not know how the new methodology for calculating federal upper limits will affect our pharmacy customers.

In addition, the Acts require CMS to publish and provide states with the weighted-average monthly AMPs for multiple source drugs. CMS has encouraged state Medicaid programs to utilize these AMPs as a benchmark for prescription drug reimbursement in place of the current, widely used benchmark of average wholesale price (AWP). CMS has not yet begun to make weighted-average AMPs available to the states or the public. When implemented, the disclosure may have the effect of reducing Medicaid reimbursement rates. We cannot predict how the public disclosure of this information may affect competition in the market place. In addition, a proposed regulation published by CMS would require state Medicaid programs to base their reimbursement rates for brand drugs on pharmacies actual acquisition costs, rather than using the current methodologies based on published benchmarks such as AWP or wholesaler acquisition cost. The proposed regulation does not establish a deadline for this transition. If this regulation is finalized as proposed, we do not know how the new Medicaid reimbursement rates will affect our pharmacy customers.

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Effective January 1, 2010, the Acts also increased the minimum Medicaid rebate rate from 15.1% to 23.1% of AMP for drugs approved under a NDA, and increased the Medicaid rebate from 11% to 13% of AMP for drugs approved under an ANDA. Also, the volume of rebated drugs has been expanded to include drugs dispensed to beneficiaries in Medicaid managed care organizations. In addition, when CMS issues final implementing regulations, which are expected in 2013, an alternative higher rebate may be imposed on drugs that are line extensions of previously approved drugs. These measures have increased our cost of selling to the Medicaid market.

The full effects of the Acts on Medicaid payment and on our Medicaid rebates cannot be known until all of these provisions are implemented and the CMS issues applicable regulations or guidance, but may have an adverse impact on our results of operations.

Any failure to comply with the complex reporting and payment obligations under the Medicare and Medicaid programs may result in further litigation or sanctions, in addition to the lawsuits.

The U.S. laws and regulations regarding Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. The subjective decisions and complex methodologies used in making calculations under these programs are subject to review and challenge, and it is possible that such reviews could result in material changes. A number of state attorneys general and others have filed lawsuits alleging that we and other pharmaceutical companies reported inflated average wholesale prices, leading to excessive payments by Medicare and/or Medicaid for prescription drugs. Such allegations could, if proven or settled, result in monetary penalties and possible exclusion from Medicare, Medicaid and other programs. In addition, we are notified from time to time of governmental investigations regarding drug reimbursement or pricing issues.

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 or 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. In addition, product liability coverage for pharmaceutical companies is becoming more expensive and, as a result, we may not be able to obtain the type and amount of coverage we desire or to maintain our current coverage.

Product recalls could harm our business.

Product recalls or product field alerts may be issued at our discretion or at the discretion of the FDA, other governmental agencies or other companies having regulatory authority for pharmaceutical product sales. From time to time, we may recall products for various reasons, including failure of our products to maintain their stability through their expiration dates. Any recall or product field alert has the potential of damaging the reputation of the product or our reputation. Any significant recalls could materially affect our sales. In these cases, our business, financial condition, results of operations and cash flows could be materially adversely affected.

Our reputation among consumers and our customers in the pharmacy trade may be negatively impacted by incidents of counterfeiting of our products.

The counterfeiting of pharmaceutical products is a widely reported problem for pharmaceutical manufacturers, distributors, retailers and consumers in the United States, which is our largest market. Such counterfeiting may take the form of illicit producers manufacturing cheaper and less effective counterfeit versions of our products, or producing imitation products containing no active ingredients, and then packaging such counterfeit products in a manner which makes them look like our products. If incidents occurred in which such products prove to be ineffective, or even harmful, to the individuals who used them, consumers and our customers might not buy our products out of fear that they might be ineffective or dangerous counterfeits. In addition, sales of counterfeit products could reduce sales of our legitimate products, which could have a material negative impact on our sales and net income.

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The manufacture and storage of pharmaceutical and chemical products are subject to environmental regulation and 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 damage caused by or during the storage or manufacture of both the chemical ingredients and the finished pharmaceutical products. Although we have never incurred any material liability for damage of this 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 pharmaceutical industry is furthermore subject to extensive environmental regulation. We therefore face the risk of incurring liability for damages or the costs of remedying environmental issues because of the chemical ingredients contained in pharmaceutical products and the nature of their manufacturing process. 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 issues 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 in 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 that the products being tested will 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 these third-parties. We have little or no control over any of these factors.

Some of our products are manufactured by independent third-parties. Any failure by any of these third-parties to perform this manufacturing properly or follow cGMPs, may have an adverse effect upon our ability to maintain regulatory approvals or continue marketing our products.

Certain products are manufactured by independent third-parties. Their compliance with cGMPs and other regulatory requirements is essential to our obtaining and maintaining regulatory approvals and marketing authorization for these products in the countries in which they are sold. Any failure by any of these third-parties to perform this manufacturing properly or follow cGMPs, may have an adverse effect upon our ability to maintain regulatory approvals or continue marketing our products.

Risks Relating to Our Company and Our Operations

Sun currently controls 77.3% of the voting power in our Company.

Dilip Shanghvi and members of his immediate family (two of whom are directors of our board of directors) currently control, through their beneficial ownership of 65.9% of our outstanding ordinary shares and 100% of our founders shares through Sun, 77.3% of the voting power in our Company. Dilip Shanghvi, along with entities controlled by him and members of his family, control 63.7% of Sun Pharma. Sun would be able to control shareholder votes requiring a majority of the votes.

50% of the voting power in our subsidiary Taro U.S.A. is held by a corporation which is controlled by Sun.

The share capital of Taro U.S.A. is divided into two classes. Taro Israel owns 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 (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. Sun owns all of the outstanding voting shares of TDC and thereby controls 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 Taro Israel 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 Taro Israel s preference, TDC could prevent Taro Israel 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 the Company from consolidating Taro U.S.A. into the Company s financial statements. Taro U.S.A. accounted for 88% of the Company s consolidated revenue for the year ended March 31, 2013, 84% of the Company s consolidated revenue for the three months ended March 31, 2012 and the year ended December 31, 2011, and 78% of the Company s consolidated revenue for the year ended December 31, 2010.

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Wholesaler customers account for a substantial portion of our consolidated sales.

We have no long-term agreements with the wholesalers that require them to purchase our products and they may therefore reduce or cease their purchases from us at any time. Any cessation or significant reduction of their purchases from us would likely have a material adverse effect on the results of our operations and our financial condition. Furthermore, changes in their buying patterns or in their policies and practices in relation to their working capital and inventory management may result in a reduction of, or a change in the timing of, their purchases of our products. While we receive periodic inventory reports from the wholesalers, we have no ability to obtain advance knowledge of such changes. We base our manufacturing schedules, inventories and internal sales projections principally on historical data. To the extent that actual orders from these wholesalers differ substantially from our internal projections, we may either find ourselves with excess inventory or in an out-of-stock position, which could have a material adverse effect upon our operating results.

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 products to wholesalers, and the wholesalers resell the products to third-parties at times and in quantities ordered by the third-parties. Typically, we have a contract price with a third-party to which a wholesaler resells our products that may be equal to or less than the price at which we sold the products to the wholesaler. In such a case, following the purchase of the product by a third-party purchaser from the wholesaler, the wholesaler charges us back for any shortfall. At the time of any individual sale by us to a wholesaler, we do not know under which contracts the wholesaler will resell products to third-parties. Therefore, we estimate the amount of chargebacks and other credits that may be associated with these sales and we reduce our revenue accordingly. One factor in calculating these estimates is information on customer inventory levels provided to us by our customers. We obtain official reports of the amount of our products held in inventory by our wholesaler customers. If this information is inaccurate or not forthcoming, this may result in erroneously estimated reserves for chargebacks, returns or other deductions. In addition, from time to time, the amount of such chargebacks and other credits reported by a wholesaler may be different from our estimates. Discrepancies of this nature may result in a reduction in the value of our accounts receivable and a related charge to net income. The reconciliation of our accounts with wholesalers may, from time to time, delay, or otherwise impact, the collection of our accounts receivable or result in a decrease in their value and in a related charge to our net income.

Our inventories of finished goods have expiration dates after which they cannot be sold.

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. However, inventories prepared for sales that are not realized as or when anticipated may approach their expiration dates and may have to be written off. These write-offs, if any, could have an adverse effect on the results of our operations and financial condition.

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

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 could negatively impact the results of our operations. Each of the steps in the development, manufacture and marketing of our products involves significant time and expense. We are, therefore, subject to the risks, among others, that:

- any products 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 new product cannot be successfully and profitably produced and marketed;

quality control problems may adversely impact our reputation for high quality production;

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other companies may launch their version of generic products, either prior to or following the launch of our newly approved generic version of the same product;

brand-name companies may 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;

generic companies may launch generic versions of our brand-name drugs; or

our products may not be priced at levels acceptable to our customers.

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

While the majority of our products are either synthesized by us or are derived from multiple source materials, some raw materials and certain products are currently obtained from single domestic or foreign 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 raw materials or products. For most raw materials we do not have any long-term supply agreements and therefore we are 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 consequently, 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.

Research and development efforts invested in our innovative pipeline may not achieve expected results.

We invest increasingly greater resources to develop our innovative pipeline, both through our own efforts and through collaborations with third-parties, which results in higher risks.

The time from discovery to a possible commercial launch of an innovative product is substantial and involves multiple stages during which the product may be abandoned as a result of serious developmental problems, the inability to achieve our clinical goals, the inability to obtain necessary regulatory approvals in a timely manner, if at all, or the inability to produce and market such innovative products successfully and profitably. In addition, we face the risk that some of the third-parties we collaborate with may fail to perform their obligations. Accordingly, our investment in research and development of innovative products can involve significant costs with no assurances of future revenues or profit.

We are continuing our efforts to develop new proprietary pharmaceutical products, but these efforts are subject to risk and may not be successful.

Our principal business has traditionally been the development, manufacture and marketing of generic equivalents of pharmaceutical products first introduced by other companies. However, we have increased our efforts to develop new proprietary products.

Expanding our focus beyond generic products and broadening our product pipeline to include new proprietary products 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 products 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 new proprietary products.

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, in the pharmaceutical industry only a small minority of all new proprietary research and development programs ultimately result in commercially successful drugs.

In order to obtain regulatory approvals for the commercial sale of new proprietary products, we are required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of the products to the satisfaction of FDA and regulatory authorities abroad. Conducting

clinical trials is a lengthy, time-consuming and expensive process, and the results of such trials are inherently uncertain. We may have limited experience in conducting clinical trials in these new product areas.

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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 new product to demonstrate safety and/or efficacy;
- the development of serious (including life threatening) adverse events (including, for example, side effects caused by or connected with exposure to the new product); or
- the failure of clinical investigators, trial monitors and other consultants or trial subjects to comply with the trial plan or protocol.

The results from early clinical trials may not be predictive of results obtained in later clinical trials. Clinical trials may not demonstrate the safety and efficacy of a product sufficient to obtain the necessary regulatory approvals, or to support a commercially viable product. 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, there can be no assurance that our proprietary products will be successful or profitable. In addition, advertising and marketing expenses associated with the launch of a proprietary product may, if not successful, adversely affect the results of our operations and our financial condition.

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

We have in the past, and may in the future, pursue acquisitions of product lines and/or companies and seek to integrate them into our operations. Acquisitions of additional product lines and companies involve risks that could adversely affect our future results of operations. Any one or more of the following examples may apply:

- we may not be able to identify suitable acquisition targets or acquire companies on favorable terms;
- we compete with other companies that may have stronger financial positions and are therefore better able 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 our acquisitions successfully in accordance with our business strategy;

we may choose to acquire a business that is not profitable, either at the time of acquisition or thereafter;

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 businesses we 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; and

we may purchase a company that has contingent liabilities that include, among others, known or unknown intellectual property or product liability claims.

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Our tax liabilities could be larger than anticipated.

We are subject to tax in many jurisdictions, and significant judgment is required in determining our provision for income taxes. Likewise, we are subject to audit by tax authorities in many jurisdictions. In such audits, our interpretation of tax legislation might be challenged and tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions under our inter-company agreements. Although we believe our estimates are reasonable, the ultimate outcome of such audits and related litigation could be different from our provision for taxes and might have a material adverse effect on our consolidated financial statements.

Risks Relating to Our Intellectual Property

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 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. Many provisions of the America Invents Act went into effect March 16, 2013 and may change or otherwise affect our ability to protect our intellectual property. 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. Where trade secrets are our sole protection, we may not be able to prevent third-parties from marketing generic equivalents to our products, reducing prices in the marketplace and reducing our profitability.

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, consultants and others. These agreements may be breached and we may not have 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 our 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 such 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 expenses, 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;
- require us to pay substantial monetary damages or royalties in order to license proprietary rights from third-parties; and
- prevent us from launching a developed, tested and approved product.

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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 United States 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 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 patented products before the related patents expire. In order to do so in the United States, we must challenge the patent under the procedures set forth in the Hatch-Waxman Act. In the United States, in order to obtain a final approval for a generic product prior to expiration of certain of the innovator s patents, we must, under the terms of the Hatch-Waxman Act, as amended by the Medicare Act, notify the patent holder as well as the owner of an NDA, that we believe that the patents listed in the Approved Drug Products with Therapeutic Equivalence Evaluations contained on the FDA website (the Orange Book) for the new drug are either invalid or not infringed by our product. 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. In addition, when seeking regulatory approval for some of our products, we are required to certify to the FDA and its equivalents in foreign countries, 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.

In addition, it is not required that pharmaceutical patents be listed with the FDA or other regulatory authorities. For example, patents relating to antibiotics might not be listed in the Orange Book. Any launch of a pharmaceutical product by us that may infringe a patent, whether listed or not, may involve us in litigation.

Patent challenges are complex, costly and can take a significant amount of time to complete. A claim of infringement and the resulting delay could result in substantial expenses and even prevent us from manufacturing and selling products and, in certain circumstances, such litigation may result in significant damages which could have a material adverse effect on the results of our operations and financial condition.

Our launch of a product prior to a final court decision, settlement with the patent owner 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 the patent holder s loss of income. If we are found to infringe a patent held by a third-party and become subject to significant damages, these damages could have a material adverse effect on the results of our operations and financial condition.

Security breaches could compromise sensitive information belonging to us and could harm our business (including our intellectual property) and reputation.

The safeguarding of our information technology infrastructure is important to our business. A cyber-attack that bypasses our information technology (IT) security systems causing an IT security breach may lead to a material disruption of our IT business systems and/or the loss of business information, resulting in adverse business impact. Adverse effects could include:

- the theft, destruction, loss, misappropriation or release of our confidential data or our intellectual property;
- operational or business delays resulting from the disruption of IT systems and subsequent clean-up and mitigation activities; and
- negative publicity resulting in reputation or brand damage with our customers, partners or industry peers.

Risks Relating to Our Compliance with Sarbanes-Oxley

We have, in the recent past, and could in the future, fail to maintain effective internal controls in accordance with Section 404 of Sarbanes-Oxley.

The Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley) imposes certain duties on us and our executives and directors. Our efforts to comply with the requirements of Sarbanes-Oxley, and in particular with Section 404 thereof, have resulted in diversion of our management s time and attention,

and we expect these efforts to require the continued commitment of resources.

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We have in the past, and may, in the future, identify material weaknesses in our internal controls that evidence that we fail to maintain effective internal controls in accordance with Section 404 of Sarbanes-Oxley. As of March 31, 2013, we eliminated all material weaknesses in internal controls that had been identified in prior years annual reports. Failure to maintain adequate internal controls could negatively affect shareholder and customer confidence.

Material weaknesses in our disclosure controls and procedures could negatively affect shareholder and customer confidence.

Under Sarbanes-Oxley, we are required to assess the effectiveness of our disclosure controls and procedures (as defined in Sarbanes-Oxley) on an annual basis. The ineffectiveness of our disclosure controls and procedures could negatively affect shareholder and customer confidence and have a material adverse impact on the market price of our ordinary shares.

Risks Relating to Investment in Our Ordinary Shares

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 may, in the future, 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 or 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;
- general economic and political conditions;
- departures of key personnel;
- changes in the market valuations of our competitors;
- regulatory considerations; and
- the other risk factors listed in this section.

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 (Controlled Foreign Corporation) under the United States Internal Revenue Code of 1986, as amended (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 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 United States 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).

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Risks Relating to Our International Operations

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 United States 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 holdings and other assets denominated in a foreign currency are greater or less than our liabilities denominated in a foreign currency, we have foreign exchange exposure.

The recent financial crisis and current uncertainty in global economic conditions could negatively affect the Company s operating results.

The recent financial crisis and ensuing uncertainty in global economic conditions have resulted in substantial volatility in the credit markets and a low level of liquidity in many financial markets. These conditions may result in a further slowdown to the global economy that could affect our business by reducing the prices that drug wholesalers and retailers, hospitals, government agencies and managed healthcare providers may be able or willing to pay for our products or by reducing the demand for our products, which could in turn negatively impact our sales and revenue generation and result in a material adverse effect on our business, cash flow, results of operations, financial position and prospects.

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

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

Risks Relating to Key Employees

Our future success is highly dependent on our continued ability to attract and retain key personnel. Any failure to do so could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our ordinary shares to decline.

The pharmaceutical industry, and our company in particular, is science based. It is therefore imperative that we attract and retain qualified personnel in order to develop new products and compete effectively. If we fail to attract and retain key scientific, technical or management personnel, our business could be affected adversely. If we are unsuccessful in retaining or replacing key employees, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our ordinary shares to decline.

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 a significant component of our manufacturing and research and development facilities are located in Israel. Political, economic and military conditions in Israel may 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. Although Israel has entered into various agreements with Egypt, Jordan and the Palestinian Authority, Israel frequently has been subject to civil unrest and terrorist activity, with varying levels of severity. The impact of civil disturbances in various countries in the Middle East may also adversely affect our operations. Furthermore, certain parties with whom we do business periodically have declined to travel to Israel, forcing us to make alternative arrangements where necessary, and the United States Department of State has issued an advisory regarding travel to Israel. As a result, 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.

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 sustained by us could have a material adverse effect on our business.

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Many male Israeli citizens, including our employees, are subject to compulsory annual reserve military service through middle age. Additionally, these employees are subject to being called to active duty at any time under emergency circumstances. Ongoing and revived hostilities with other countries might require more widespread military reserve service by some of our employees. Our operations could be disrupted by 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 could harm our business.

We may be affected by fluctuations in the NIS relative to 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 United States dollars, is subject to the risk of exchange rate fluctuations among the U.S. dollar and the NIS. During the year-ended March 31, 2013, the value of the NIS increased 1.8% with respect to the United States dollar. Such an increase adversely affects our United States dollar-measured results of operations.

Our operations may be affected by negative labor conditions in Israel.

Strikes and work-stoppages occur relatively frequently in Israel. If Israeli trade unions threaten additional strikes or work-stoppages and such strikes or work-stoppages occur, those may, if prolonged, have a material adverse effect on the Israeli economy and on our business, including our ability to deliver products to our customers and to receive raw materials from our suppliers in a timely manner.

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

All pharmaceutical products sold in Israel are subject to government price controls. Permitted price increases and decreases 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 may benefit from government programs and tax benefits, both or either of which may be discontinued or reduced.

We have, in the past, received 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 Ministry of Industry, Trade and Labor of the State of Israel (OCS). In order to be eligible for these programs and benefits, we must 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 could restrict our ability to manufacture particular products and 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 payments and/or taxes. In the future, the government of Israel may discontinue or curtail these and the tax benefits available under these programs. If the government of Israel ends these programs and tax benefits while we are recipients, our business, financial condition and results of operations could be materially adversely affected.

Provisions of Israeli law may delay, prevent or make more difficult a merger or acquisition. This 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 more difficult a merger or acquisition. The Israeli Companies Law, 1999 (the Israeli Companies Law) and the regulations promulgated thereunder, generally require that a merger be approved by a company s board of directors and by a shareholder vote at a shareholders meeting that has been called on at least 35 days advance notice by each of the merger parties. Under our Articles of Association, the required shareholder vote is a supermajority of at least 75% of the shares voting in person or by proxy on the matter. 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 50 days have passed from the time that a merger proposal has been delivered to the Israeli Registrar of Companies and at least 30 days have passed from the time each merging company received shareholder approval.

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 Israeli Companies Law. Until this happens, uncertainties will exist regarding its interpretation.

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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 United States 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 more difficult a merger or acquisition. This could prevent a change of control of the Company 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 our directors and officers.

We are incorporated in Israel. The majority of our executive officers and directors are non-residents 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 United States federal securities laws in original actions instituted in Israel.

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 countries where we operate. We cannot predict the extent to which we may be affected by legislative and other regulatory developments concerning our products.

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

We are subject to legislation in Israel, primarily relating to patents and data exclusivity provisions. Modifications of this legislation or court decision regarding this legislation may adversely affect us and may 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 us to move production outside of Israel or otherwise adversely affect our ability to export certain products from 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 (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.

In each province of Canada there is a drug benefit formulary. A formulary lists the drugs for which a provincial government will reimburse qualifying persons and the prices at which the government will reimburse such persons. There is not complete uniformity among provinces. However, provincial governments generally will reimburse the lowest available price of the generic equivalents of any drug listed on the formulary list of the province. The formularies can also provide for drug substitution, even for patients who do not qualify for government reimbursement. The effect of these provincial formulary regimes is to encourage the sale of lower-priced versions of pharmaceutical products. The potential lack of reimbursement represents a significant threat to our business. Additionally, the substitution effect may adversely affect our ability to profitably market our products.

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We may be adversely affected if the rate of inflation in Canada exceeds the rate of devaluation of the Canadian dollar against the United States dollar.

A substantial portion of our expenses, primarily labor, occupancy, marketing and research and development expenses in Canada, is incurred in Canadian dollars. As a result, the cost of our operations in Canada, as measured in United States dollars, is subject to the risk that the rate of inflation in Canada will exceed the rate of devaluation of the Canadian dollar in relation to the United States dollar or that the timing of any devaluation will lag behind inflation in Canada. During the year-ended March 31, 2013, the value of the Canadian dollar decreased 1.7% with respect to the United States dollar. This decrease in the value of the Canadian dollar has had the effect of decreasing the United States dollar cost of our goods manufactured in Canada. If the United States dollar cost of our operations in Canada continues to decrease, our United States dollar-measured results of operations will continue to be positively affected, however, if the value of the Canadian dollar increases in the future it may have an adverse effect on our results of operations.

ITEM 4. INFORMATION ON THE COMPANY

A. HISTORY AND DEVELOPMENT OF THE COMPANY

The legal and commercial name of our company is Taro Pharmaceutical Industries Ltd. We were incorporated under the laws of the State of Israel in 1959 under the name Taro-Vit Chemical Industries Ltd. In 1984, we changed our name to Taro Vit Industries Ltd. and in 1994 we changed our name to Taro Pharmaceutical Industries Ltd., which was the name of a subsidiary of Taro Vit Industries Ltd. incorporated under the laws of the State of Israel in 1950.

In 1961, we completed the initial public offering of our ordinary shares. In that year, we also acquired 97% of the outstanding stock of an Israeli corporation, then known as Taro Pharmaceutical Industries Ltd. (TPIL), which was founded in 1950. In 1981, we sold 37% of our interest in TPIL. In 1993, after acquiring all of the outstanding shares of TPIL, we merged TPIL into our company. In July 2001, we completed a stock split by distributing one ordinary share for each ordinary share then outstanding and one ordinary share for every ten founders shares then outstanding. In October 2001, we sold 3,950,000 of our ordinary shares, and shareholders sold 1,800,000 of our ordinary shares, in a public offering. Since March 22, 2012, our ordinary shares have been traded on the NYSE under the symbol TARO.

Our registered office is located at 14 Hakitor Street, Haifa Bay 26110, Israel. Our telephone number at that address is +972-4-847-5700. Our agent for service of process in the United States is Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Drive, Hawthorne, NY 10532. Our telephone number at that address is +1-914-345-9000.

Capital Expenditures

During the year ended March 31, 2013, the three months ended March 31, 2012, and the years ended December 31, 2011 and 2010, our capital expenditures were $9.5 million, $1.6 million, $6.3 million and $5.7 million, respectively. The focus of our capital expenditure program has been the expansion and upgrade of our manufacturing facilities and information technology systems in order to enable us to increase operational efficiencies, remain in compliance with cGMP, accommodate anticipated increased demand for our products, and maintain a competitive position in the marketplace.

The major projects undertaken during these three years, as part of our capital expenditure program, include:

- the acquisition of additional production and packaging equipment;
- expanding and upgrading our research and development laboratories in Israel and Canada; and
- the upgrade of our information technology systems.

For a detailed presentation of our property, plant and equipment, see Note 7 to our consolidated financial statements included elsewhere in this 2013 Annual Report. Also see Item 4.D. Property, Plant and Equipment.

B. BUSINESS OVERVIEW

We are a multinational, science-based pharmaceutical company. We develop, manufacture and market prescription and OTC pharmaceutical products primarily in the United States, Canada and Israel. Our primary areas of focus include pediatric creams and ointments, liquids, capsules and tablets, mainly in the dermatological and topical, cardiovascular, neuropsychiatric and anti-inflammatory therapeutic categories. Nystatin/Triamcinolone accounted for 14.1% of our sales in fiscal year ended March 31, 2013.

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We operate principally through three entities: Taro Pharmaceutical Industries Ltd. (Taro Israel), and two of its subsidiaries (including indirect), Taro Pharmaceuticals Inc. (Taro Canada) and Taro U.S.A. The principal activities and primary product lines of these subsidiaries may be summarized as follows:

Entity	Principal Activities	Primary Product Lines
Taro Israel	Manufactures more than 160 finished dosage form pharmaceutical products for sale in Israel and for export	Dermatology: Prescription and OTC semi-solid products (creams, ointments and gels) and liquids
	Produces APIs used in the manufacture of finished dosage form pharmaceutical products	
	Markets and distributes both proprietary and generic products in the local Israeli market	Cardiology and Neurology: Prescription oral dosage products
	Performs research and development	
		Oral analgesics, prescription and OTC
		OTC oral and nasal sprays and ophthalmic products
Taro Canada	Manufactures more than 70 finished dosage form pharmaceutical products for sale in Canada and for export	Dermatology: Prescription and OTC semi-solid products (creams, ointments and gels) and liquids
	Markets and distributes both proprietary and generic products in the Canadian market	Cardiology, Oncology, Gastrointestinal and Neurology: Prescription oral and injectable dosage products
	Performs research and development	
		Allergy (Antihistamine): OTC oral dosage products
Taro U.S.A.	Markets and distributes both proprietary and generic products in the U.S. market	Dermatology: Prescription and OTC semi-solid products (creams, ointments and gels) and liquids
	Performs research and development	
		Cardiology and Neurology: Prescription oral dosage products
		Other prescription and OTC products

As of March 31, 2013, 22 of our products were being reviewed by the FDA. During the fiscal year ended March 31, 2013, Taro filed nine ANDAs and one NDA with the FDA. In addition, there are several products for which either development or internal regulatory work is in process. The applications pending before the FDA are at various stages in the review process, and there can be no assurance that we will be able to successfully complete any remaining testing or that, upon completion of such testing, approvals will be granted. In addition, there can be no assurance that the FDA will not grant approvals for competing products submitted by our competitors, prior to, simultaneous with or after granting approval to us.

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The Generic Pharmaceutical Industry

Generic pharmaceuticals are the chemical and therapeutic equivalents of brand-name drugs and are typically marketed after the patents for brand-name drugs have expired. Generic pharmaceuticals generally must undergo clinical testing that demonstrates that they are bioequivalent to their branded equivalents and are manufactured to the same standards. Proving bioequivalence generally requires data demonstrating that the generic formulation results in a product whose rate and extent of absorption are within an acceptable range of the results achieved by the brand-name reference drug. In some instances, bioequivalence can be established by demonstrating that the therapeutic effect of the generic formula falls within an acceptable range of the therapeutic effects achieved by the brand-name reference drug.

Generic pharmaceutical products must meet the same quality standards as branded pharmaceutical products although they are generally sold at prices that are substantially lower than those of their branded counterparts. As a result, generic pharmaceuticals represent a much larger percentage of total drug prescriptions dispensed than their corresponding percentage of total sales. This discount tends to increase (and margins tend to decrease) as the number of generic competitors increases for a given product. Because of this pricing dynamic, companies that are among the first to develop and market a generic pharmaceutical tend to earn higher profits than companies that subsequently enter the market for that product. Furthermore, products that are difficult to develop or are intended for niche markets generally attract fewer generic competitors and therefore may offer higher profit margins than those products that attract a larger number of competitors. However, profit is influenced by many factors other than the number of competitors for a given drug or the size of the market. Depending on the actions of each of our competitors, price discounts can be just as significant for a specific product with only a few competitors or a small market, as for a product with many competitors or a large market.

In recent years, the market for generic pharmaceuticals has grown. We believe that this growth has been driven by the following factors, among others:

- efforts by governments, employers, third-party payers and consumers to control healthcare costs;
- increased acceptance of generic products by physicians, pharmacists and consumers; and
- the increasing number of pharmaceutical products whose patents have expired and are therefore subject to competition from, and substitution by, generic equivalents.

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Products

We currently market more than 180 pharmaceutical products in over 25 countries. The following table represents some of our key product groups and the major markets in which they are sold:

Generic Name	Dosage Form	Brand Name[1]	Therapeutic Category	Major Markets	Rx/OTC
Acetazolamide	tablets	Diamox®	Diuretic	U.S., Israel	Rx
Acetaminophen, Codeine and Caffeine	tablets, gelcaps	Rokacet®(2)	Analgesic	Israel	OTC
Adapalene	gel	Differin®	Dermatologics and topicals	U.S.	Rx
Amiodarone Hydrochloride	tablets	Cordarone®	Cardiovascular	U.S.	Rx
Ammonium Lactate	cream, lotion	Lac-Hydrin®	Dermatologics and topicals	U.S., Canada	Rx
Augmented Betamethasone Dipropionate	lotion	Diprolene AF®	Dermatologics and topicals	U.S.	Rx
Betamethasone Valerate	cream, ointment, lotion	Celestoderm®	Dermatologics and topicals	Canada	Rx
Calcipotriene	ointment	Dovonex®	Dermatologics and topicals	U.S.	Rx
Carbamazepine	tablets, controlled release tablets, chewable tablets, oral suspension	Tegretol®	Anticonvulsant	U.S., Israel, Canada	Rx
Cetirizine Hydrochloride	solution	Zyrtec®	Allergy	U.S.	OTC
Clobetasol Propionate	cream, ointment, gel, topical solution	Temovate®	Dermatologics and topicals	U.S., Canada	Rx
Clomipramine Hydrochloride	capsule	Anafranil®	Neuropsychiatric	U.S.	Rx
Clorazepate Dipotassium	tablets	Tranxene®	Neuropsychiatric	U.S.	Rx
Clotrimazole	cream, topical solution, vaginal cream	Lotrimin® Gyne-Lotrimin®	Dermatologics and topicals	U.S., Canada	Rx/OTC
Clotrimazole and Betamethasone Dipropionate	cream, lotion	Lotrisone®	Dermatologics and topicals	U.S., Israel	Rx
Desonide	cream, ointment	Tridesilon®	Dermatologics and topicals	U.S.	Rx
Desoximetasone	cream, ointment, gel	Topicort®(2)	Dermatologics and topicals	U.S.	Rx
Diflorasone Diacetate	cream, ointment	Psorcon®	Dermatologics and topicals	U.S.	Rx
Docusate Sodium	capsule	Colace®	Gastrointestinal	Canada	OTC
Econazole Nitrate	cream	Spectazole®	Dermatologics and topicals	U.S.	Rx
Enalapril Maleate	tablets	Vasotec®	Cardiovascular	U.S.	Rx
Enalapril Maleate and Hydrochlorothiazide	tablets	Vaseretic®	Cardiovascular	U.S.	Rx
Etodolac	tablets, capsules, extended release tablets	Etopan®(2) Lodine®	Anti-Inflamatory & Analgesic	U.S., Israel	Rx
Fluconazole	tablets	Diflucan®	Dermatologics and topicals	U.S.	Rx
Fluocinonide		Lidex®		U.S., Canada	Rx

	cream, ointment, gel, topical solution		Dermatologics and topicals		
Fluorouracil	topical solution, cream	Efudex®	Topical Anti-neoplastic	U.S.	Rx
Halobetasol Propionate	cream, ointment	Ultravate®	Dermatologics and topicals	U.S.	Rx
Hydrocortisone Valerate	cream, ointment	Westcort®	Dermatologics and topicals	U.S., Canada	Rx
Hydrocortisone	cream, ointment	Cortizone 10®	Dermatologics and topicals	U.S., Canada	Rx/OTC
Hydroquinone	cream	Lustra®(2)	Dermatologics and topicals	U.S., Canada	Rx
Imiquimod	cream	Aldara®	Dermatological and topcial	U.S.	Rx
Ketoconazole	tablets, cream	Nizoral®	Dermatologics and topicals / Antifungal	U.S., Canada	Rx
Lamotrigine	tablets	Lamictal®	Anticonvulsant	U.S.	Rx
Loratadine	solution, tablets	Claritin®	Allergy	U.S., Canada	OTC
Malathion	lotion	Ovide®(2)	Dermatologics and topicals	U.S.	Rx
Metronidazole	gel	MetroGel®	Dermatologics and topicals	U.S.	Rx
Miconazole Nitrate	vaginal cream, cream	Monistat® 3 Monistat® 7 Micatin®	Dermatologics and topicals	U.S., Canada	OTC
Mometasone Furoate	cream, ointment, lotion	Elocon®	Dermatologics and topicals	U.S., Canada	Rx
Mupirocin	ointment	Bactroban®	Dermatologics and topicals	Canada	Rx
Nystatin	oral suspension, vaginal cream	Mycostatin®	Dermatologics and topicals	U.S., Israel, Canada	Rx
Nystatin/Triamcinolone	cream, ointment	Mycogen® II, Mycolog® II, Myconel®	Antifungal	U.S.	Rx
Ondansetron Hydrochloride	solution	Zofran®	Antinauseant	U.S.	Rx