

TARO PHARMACEUTICAL INDUSTRIES LTD
Form 20-F
June 21, 2018

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

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended March 31, 2018

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 2624761, Israel

(Address of principal executive offices)

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

Title of each class	Name of each exchange on which registered
Ordinary Shares, NIS 0.0001 nominal (par) value per share	New York Stock Exchange

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

None

(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:

39,427,515 Ordinary Shares, NIS 0.0001 nominal (par) value per share, and 2,600 Founders' Shares NIS 0.00001 nominal (par) value per share outstanding as of March 31, 2018

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

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

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Large accelerated filer: Accelerated filer: Non-accelerated filer: Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act:

† The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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

U.S. GAAP International Financial Reporting Standards as issued Other

by the International Accounting Standards Board

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 No

INTRODUCTION

We, among other business activities, develop, manufacture and market prescription (“Rx”) 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. Our ordinary shares have been listed on the New York Stock Exchange (the “NYSE”) under the symbol “TARO,” since March 22, 2012.

As used in this Annual Report on Form 20-F for the fiscal year ended March 31, 2018 (the “2018 Annual Report”), the terms “we,” “us,” “our,” “Taro” and the “Company” mean Taro Pharmaceutical Industries Ltd. (“Taro Israel”) and its subsidiaries unless otherwise indicated.

This 2018 Annual Report is being filed in respect of the fiscal year ended March 31, 2018, and contains the audited consolidated financial statements for the year then ended.

FORWARD-LOOKING STATEMENTS

Except for the historical information contained in this 2018 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—Risk Factors” and elsewhere in this 2018 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 2018 Annual Report are reported in U.S. 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 2018 Annual Report may not total correctly due to rounding of numbers.

All references in this 2018 Annual Report to “dollars,” or “\$,” are to U.S. dollars, all references in this Annual Report to “NIS” are to New Israeli Shekel, and all references in this Annual Report to “CAD” are to Canadian dollars. The published ⁽¹⁾ representative exchange rate between the NIS and the dollar for March 31, 2018 was NIS 3.51 per \$1.00. The published ⁽²⁾ representative exchange rate between the CAD and the dollar for March 31, 2018 was CAD 1.29 CAD per \$1.00. No representation is made that the NIS amounts or CAD 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 Bloomberg L.P.

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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.

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ITEM 3. KEY INFORMATION

A. SELECTED FINANCIAL DATA

We have derived the following selected consolidated financial data for the years ended March 31, 2018, 2017 and 2016, and as of March 31, 2018 and March 31, 2017, from our audited consolidated financial statements set forth elsewhere in this 2018 Annual Report, which have been prepared in accordance with U.S. GAAP. We have derived the consolidated selected financial data for the years ended March 31, 2015 and 2014, 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 2018 Annual Report.

	Year Ended March 31,				
	2018	2017	2016	2015	2014
	U.S. dollars and shares in thousands (except per share data)				
Consolidated Statements of Operations Data:					
Sales, net	\$661,913	\$879,387	\$950,751	\$862,944	\$759,285
Cost of sales	198,405	207,860	169,743	186,359	179,279
Impairment	—	276	2,042	—	—
Gross profit	463,508	671,251	778,966	676,585	580,006
Operating expenses:					
Research and development	70,418	70,644	71,160	65,510	55,430
Selling, marketing, general and administrative	88,196	85,656	92,365	87,644	91,733
Settlements and loss contingencies	1,884	—	973	(4,200)	2,590
	160,498	156,300	164,498	148,954	149,753
Operating income	303,010	514,951	614,468	527,631	430,253
Financial expenses (income), net	12,531	(34,636)	(19,672)	(51,311)	(12,285)
Other gain, net	1,889	11,211	2,680	2,738	1,369
Income before income taxes	292,368	560,798	636,820	581,680	443,907
Tax expense	81,954	103,780	95,313	96,059	82,729
Income from continuing operations	210,414	457,018	541,507	485,621	361,178
Net loss from discontinued operations					
attributable to Taro	(335)	(352)	(236)	(787)	(319)
Net income	210,079	456,666	541,271	484,834	360,859
Net (loss) income attributable to non-controlling interest	(1,071)	310	339	577	472
Net income attributable to Taro	\$211,150	\$456,356	\$540,932	\$484,257	\$360,387
Net income from continuing operations attributable					
to Taro	\$211,485	\$456,708	\$541,168	\$485,044	\$360,706
Net loss from discontinued operations					
attributable to Taro	(335)	(352)	(236)	(787)	(319)
Net income attributable to Taro	\$211,150	\$456,356	\$540,932	\$484,257	\$360,387
Net income per ordinary share from continuing					

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operations attributable to Taro:					
Basic and Diluted	\$5.27	\$11.06	\$12.63	\$11.32	\$8.15
Net loss per ordinary share from					
discontinued operations attributable to Taro:					
Basic and Diluted	\$(0.01)	\$(0.01)	\$(0.01)	\$(0.01)	\$(0.01)
Net income per ordinary share attributable to Taro:					
Basic and Diluted	\$5.26	\$11.05	\$12.62	\$11.31	\$8.14
Weighted-average number of ordinary shares used to					
compute net income per share:					
Basic	40,155	41,301	42,832	42,834	44,276
Diluted	40,155	41,301	42,832	42,834	44,279

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	As of March 31,				
	2018	2017	2016	2015	2014
	(U.S. dollars in thousands)				
Consolidated Balance Sheet Data:					
Working capital	\$1,680,879	\$1,789,187	\$1,632,133	\$1,203,802	\$797,967
Property, plant and equipment, net	\$193,727	\$180,085	\$159,459	\$153,045	\$151,416
Total assets	\$2,433,210	\$2,289,753	\$2,188,033	\$1,737,745	\$1,284,376
Short-term debt, including current maturities of					
long-term debt	\$—	\$—	\$—	\$912	\$11,974
Long-term debt, net of current maturities	\$—	\$—	\$—	\$4,976	\$5,888
Shareholders' equity	\$2,210,399	\$2,073,806	\$1,937,144	\$1,417,383	\$1,020,593

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

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.

Our net sales and quarterly growth comparisons may also be affected by fluctuations in the buying patterns of retail chains, major distributors and other trade buyers, whether resulting from seasonality, pricing, wholesaler buying decisions or other factors. In addition, since such a significant portion of our U.S. revenue is derived from relatively few customers, any financial difficulties experienced by a single customer, or any delay in receiving payments from a single customer 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.

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.

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We anticipate that we will face increased competition and product price erosion 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.

Reductions in pharmaceutical pricing may adversely affect our business.

Pharmaceutical pricing, through the current administration, political, social, and other pressure, has been subjected to increased scrutiny. Our pricing and profitability may be affected, which may have a material adverse effect on our business, financial condition and results of operation.

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 us 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 may 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 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.

We may be unable to take advantage of the increasing number of high-value biosimilar opportunities.

Biosimilar products are expected to make up an increasing proportion of the high-value generic opportunities in upcoming years. The development, manufacture and commercialization of biosimilar products require specialized expertise and are very costly and subject to complex regulation, which is still evolving. We will require significant investments and collaborations with third parties to take advantage of these opportunities. We cannot assure you that any future investments and collaborations regarding biosimilar products will be successful.

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, among other things, the approval, testing, manufacture, labeling, marketing, sale, import and export 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 pre-clinical and 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. In addition to bioequivalence testing, the generic product must also have the same dosage form, strength, route of administration and intended use as the innovator drug product. 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 products are limited by statutes and regulations and, with respect to our generic drugs, by the claims approved by the FDA for the brand-name product. In addition, if the FDA and/or a foreign regulatory authority approves any of our products, the labeling, packaging, adverse event reporting, storage conditions, advertising and promotion for the product will be subject to extensive and ongoing regulatory requirements. Further, as a manufacturer of pharmaceutical products distributed in the United States, we must also continue to comply with cGMP regulations, which include requirements related to production processes, quality control and quality 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 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, warning or untitled letters, consent decrees or civil or criminal penalties. Taro shares common ownership with Ranbaxy Inc. through acquisitions made by Sun. In 2012, Ranbaxy Inc. entered into a Consent Decree of Permanent Injunction with the FDA which decree gives the FDA authority to impose its terms and obligations on any “subsidiary” or “affiliate” of Ranbaxy Inc. Also, if such deviations occurred, it is unclear if the FDA could extend the existing Consent Decree of Permanent Injunction, applicable to Ranbaxy Inc. to a facility owned or operated by Taro in light of the companies' common ownership by Sun. 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 and Canada, we must meet the requirements of the Controlled Substances Act in the United States and its equivalents in Israel and Canada, as well as the regulations promulgated thereunder in each country. These regulations include stringent requirements for registration, manufacturing controls, importation, distribution, exportation, 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 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.

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 warning or untitled letters, 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.

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 could deprive the first "Paragraph IV" filer (as described below) of eligibility for such 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 listed drug that it references in its ANDA. 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 Paragraph IV certification. The Hatch-Waxman Act provides for a potential 180-day period of generic exclusivity for the first company that submits an ANDA with a Paragraph IV certification and that also lawfully maintains such certification. Such exclusivity prevents the approval for 180 days 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 receipt of notification to the patent holder of the Paragraph IV filing, provided there are no other issues preventing the FDA from granting final approval. Exclusivity rights for the first Paragraph IV filer may be forfeited pursuant to the Medicare Act under specified circumstances including, for example, if tentative approval is not timely obtained. 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; other earlier submitted ANDAs are generally governed by the previous version of the law.

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

We 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.

Healthcare reform may have an impact on all segments of the healthcare industry.

In March 2010, the U.S. government enacted the Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act of 2010 (collectively, "PPACA"), which represented the most comprehensive overhaul of both the public and private healthcare systems ever enacted in the United States.

The PPACA imposes on manufacturers a variety of additional rebates, discounts, fees, taxes and reporting and regulatory requirements. Changes to the healthcare system enacted as part of healthcare reform in the United States, as well as the increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, may result in increased pricing pressure by influencing, for instance, the reimbursement policies of third-party payors. We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our products.

We face uncertainties due to federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. Despite the recent failure of the Senate's attempts to repeal various combinations of such PPACA provisions, these and similar actions by the current administration are widely expected to lead to fewer Americans having comprehensive PPACA compliant health insurance, even in the absence of a legislative repeal. There is no assurance that any future replacement, modification or repeal of the PPACA will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

Reimbursement policies of third-parties, cost containment measures and healthcare reform as well as governmental regulation of prices 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 prices and reimbursement levels for them and related treatment established by federal and state government healthcare programs, private health insurers and other third party payor 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 our prices or 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 any federal, state or other governmental authority enacts any additional legislation or adopts any additional regulations or policies that affect third-party coverage, price levels or 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, drug prices and government insurance programs; and
- price regulation and controls and reimbursement policies.

The PPACA is a sweeping measure intended to expand healthcare coverage in the U.S., primarily through the establishment of an exchange to facilitate the purchase of health insurance, premium and cost-sharing subsidies for certain low-income individuals, the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Among other things, the PPACA contained provisions that changed payment levels for pharmaceuticals under Medicaid and increased pharmaceutical rebates under the Medicaid Drug Rebate Program. Effective October 1, 2010, the law changed the formula for calculating federal upper limits ("FULs"), 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 therapeutically equivalent versions on the market). The FULs are 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 for drugs distributed to retail community pharmacies. The Centers for Medicare & Medicaid Services ("CMS") issued final regulations regarding the FUL and the calculation of AMP and rebates under the Medicaid Drug Rebate Program. These regulations were effective as of April 1, 2016. Even though the weighted-average does not disclose our AMP, the release of such FULs to the public and our customers may affect our pricing.

In addition, in its final regulations for the Medicaid Drug Rebate Program, CMS required state Medicaid programs, beginning April 1, 2017, to base their reimbursement rates for brand drugs and other drugs not subject to a FUL on pharmacies' actual acquisition costs, rather than using the current methodologies based on published benchmarks such as average wholesale price ("AWP") or wholesaler acquisition cost. We do not yet know the full impact of the new Medicaid reimbursement rates on our pharmacy customers.

Effective January 1, 2010, the PPACA also increased the minimum Medicaid rebate rate from 15.1% to 23.1% of AMP for most drugs approved under a new drug application ("NDA"), including authorized generics. The PPACA also

increased the Medicaid rebate from 11% to 13% of AMP for most drugs approved under an ANDA. Further, the volume of rebated drugs has been expanded to include drugs dispensed to beneficiaries in Medicaid managed care organizations. In addition, an alternative, higher rebate may be imposed on drugs that are line extensions of previously approved oral dosage form drugs. CMS's final regulations also expanded the Medicaid Drug Rebate Program such that manufacturers will be required to pay rebates to Puerto Rico and the U.S. Territories (the U.S. Virgin Islands, Guam, the Northern Mariana Islands and American Samoa), effective April 1, 2020. These measures have increased or will increase our cost of selling to the Medicaid market.

Furthermore, as a result of legislative changes in the Bipartisan Budget Act of 2015 ("BBA"), effective for the first calendar quarter of 2017, generic drugs are subject to an additional rebate if the AMP for a given quarter exceeds an inflation-adjusted baseline AMP. This price increase penalty previously applied only to innovator drugs.

The full effects of the PPACA and the BBA on Medicaid payments and on our Medicaid rebates cannot be known at this time, in part because not all of these provisions have been implemented yet, but they may have an adverse impact on our results of operations. In addition, recently, the current administration has made statements that it supports repeal of all or portions of the PPACA, and Congress recently enacted new legislation that repealed key portions of the PPACA. There is uncertainty with respect to the impact these changes, if any, may have, and any changes likely will take time to unfold. Any additional federal healthcare reform measures adopted in the future could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

Our relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any products we market. Our arrangements with third-party payors, prescribers, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare program anti-kickback statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal law requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals on an annual basis, which includes data collection and reporting obligations. The information is made publicly available on a searchable website; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures. Still other states require the reporting of certain pricing information, including information pertaining to and justification of the price increases greater than a specified threshold, or prohibit prescription drug price gouging. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our business

practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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 calculating prices that are reportable 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 pharmaceutical companies reported inflated AWP, leading to excessive payments by Medicare and/or Medicaid for prescription drugs. Additional actions are possible. These actions, if successful, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

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, in the future, 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 as recommended or required by the FDA, other governmental agencies or other companies having regulatory authority over 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.

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 property damage or personal injury 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 also subject to extensive environmental regulation. We therefore face the risk of incurring liability for damages or the costs of remedying environmental harms because of the chemical ingredients contained in our products and the processes involved with their manufacture. For example, we could be held liable for costs to investigate or remediate contamination resulting from the presence or release of hazardous materials at or from any of our properties or the disposal of any such materials at third party sites. 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 address environmental issues and to comply with applicable regulations. If we fail to comply with environmental regulations or the conditions of 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 Pharmaceutical Industries Ltd., and its affiliates, currently controls 83.2% of the voting power in our Company.

Our Chairman, Dilip Shanghvi and members of his immediate family (one of whom is a member of our board of directors) currently control, through their beneficial ownership of 74.8% of our outstanding ordinary shares and 100% of our founders' shares through Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) ("Sun Pharma" and its affiliates, "Sun"), 83.2% of the voting power in our Company, as of March 31, 2018. Dilip Shanghvi, along with entities controlled by him and members of his family, control 54.4% of Sun Pharma as of March 31, 2018. Sun is able to control the outcome of 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 81%, 88% and 90% of the Company's consolidated revenue for the years ended March 31, 2018, 2017 and 2016, respectively.

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 our results of operations and 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, our results of 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 our results of 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 our results of 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;
 - 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. Most of these materials are subject to regulatory inspections and if found to be non-compliant we could be prevented from obtaining them. 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 to us 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.

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 our results of operations and financial condition.

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

We have in the past, and may in the future, pursue licensing deals (both in-license and out-license deals) or acquisitions of product lines and/or companies and seek to integrate them into our operations. Licensing deals and 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 encounter issues with intellectual property, manufacturing or financial complications with in-license or out-license deals;
- we may not be able to identify suitable licensing deals, 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 licenses, product lines and companies. We believe that this competition will increase and may result in decreased availability or increased prices for suitable licenses or acquisition targets;
- we may not be able to obtain the necessary financing, on favorable terms or at all, to finance any of our potential license deals or 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 licenses or acquisitions;
- we may ultimately fail to complete a licensing deal or an acquisition after we announce that we plan to license a product or acquire a product line or a company;
- we may fail to license products or integrate our acquisitions successfully in accordance with our business strategy;
- we may choose to license a product or acquire a business that is not profitable, either at the time of the license or acquisition or thereafter;
- licensing deals or acquisitions may require significant management resources and divert attention away from our daily operations, resulting 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 maximize an in-license's profitability or 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 license a product or purchase a company that has contingent liabilities that include, among others, known or unknown intellectual property or product liability claims.

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 intercompany 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.

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (the "Tax Act"), which among other provisions, reduced the U.S. corporate tax rate from 35% to 21%, effective January 1, 2018. Fiscal year filers, such as Taro USA, recognize a partial reduction in the U.S. corporate tax rate for their year ending after January 1, 2018 and thereafter recognize the full reduction in the U.S. corporate tax rate. For the year ended March 31, 2018 Taro USA is subject to a 31.5% federal tax rate and for subsequent years Taro USA is subject to a 21% federal tax rate. Taro USA re-measured its deferred tax assets and liabilities, based on the 21% rate. The estimated tax cost recorded related to the re-measurement of the deferred tax balance was \$38.0 million.

The Tax Act changed the manner in which companies may utilize losses carried forward. For losses in tax years ending after December 31, 2017 losses may carry forward an unlimited number of years, however losses may only offset 80% of the federal taxable income in each future year. Taro USA generated an estimated \$22.6 million loss during the year ended March 31, 2018 and this estimated loss is subject to the above changes. The Tax Act created a

variety of other taxes and incentives; however, the Company currently believes these other provisions have limited or no impact on Taro USA. We are still in the process of evaluating the impact on future years.

We are in the process of enhancing and further developing our global enterprise resource planning systems and associated business applications, which could result in business interruptions if we encounter difficulties.

We are enhancing and further developing our global enterprise resource planning (“ERP”), quality control laboratory operations systems and other business critical information technology (“IT”) infrastructure systems and associated applications to provide more operating efficiencies and effective management of our business and financial operations. Such changes to ERP systems and related software, quality control systems, and other IT infrastructure carry risks such as cost overruns, project delays and business interruptions and delays. If we experience a material business interruption as a result of our ERP enhancements, it could have a material adverse effect on our business, financial position, and results of operations and/or cash flow.

We are increasingly dependent on information technology and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

We are increasingly dependent on sophisticated information technology systems and infrastructure to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, trade secrets, intellectual property, proprietary business information, and employee personal information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have contracted with third party vendors to enhance our operations and, as part of our service arrangements with Sun as described in greater detail under “Item 7B —Related Party Transactions—Related Party Transactions—Arrangements with Sun.” We also have outsourced elements of our operations to Sun, including significant elements of our information technology infrastructure. The size and complexity of our information technology systems, and those with whom we contract, make such systems potentially vulnerable to service interruptions, security breaches from inadvertent or intentional actions by employees, partners or vendors, or from attacks by malicious third parties. Any significant disruptions to our information technology systems, including breaches of information security or cybersecurity, or failure to integrate new and existing information technology systems could adversely affect our business, financial condition or results of operations. While we exercise care in selecting vendors that maintain adequate information security controls and monitor our relationships with our vendors, we and our vendors or Sun, could be susceptible to third party attacks on our information security systems, which attacks are of ever increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including state and quasi-state actors, criminal groups, “hackers” and others. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry.

Maintaining the secrecy of our confidential information, trade secrets, intellectual property, proprietary business information, and employee personal information is important to our competitive business position. However, such information can be difficult to protect. While we have taken steps to protect such information and invested heavily in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of data that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of our data, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our data to gain an advantage, and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

Social media presents potential internal and external harm for our company.

The internal unauthorized, inappropriate or illicit use of social media could cause reputational harm to our business and/or create adverse consequences, including the inadvertent release of non-public information or personally identifiable information. Externally, our brand and reputation could suffer harm in the event of negative comments or altered information being disseminated through social media. If we were to suffer reputational or brand harm or adverse consequences through social media, it may have a material adverse effect on our business, financial condition and results of operations.

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, or may challenge our own proprietary rights.

There has been substantial litigation in the pharmaceutical industry with respect to the manufacture, use and sale of new products. These lawsuits often 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;
- prevent us from launching a developed, tested and approved product; or
- result in our loss of certain patent or proprietary rights.

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 invalid, unenforceable 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, enforceability 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, or that those patents are invalid or unenforceable. Filing a certification against a patent gives the patent holder the

right to bring a patent infringement lawsuit against us. Any lawsuit in the United States would delay regulatory approval by the FDA until the earlier of the resolution of such claim or 30 months from the patent holder's receipt of notice of certification.

A third party might challenge any of our patent rights. If successful, such a challenge could result in a loss of market exclusivity with respect to one or more of our products.

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 our results of 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 up to three times the patent holder's loss of profit or other actual damages, and not less than a reasonable royalty. 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 our results of operations and financial condition.

Risks Relating to Our Compliance with the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley")

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

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.

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, 2018, we did not identify any material weaknesses in internal controls. 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 on an annual basis. If we were to conclude that our disclosure controls and procedures were ineffective, shareholder and customer confidence could be negatively affected, which could 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;
- failure by us to develop new products;
- 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 of this 2018 Annual Report.

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

In order to reduce our risk of being classified as a “Controlled Foreign Corporation” under the United States Internal Revenue Code of 1986, as amended (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). As of March 31, 2018, no citizen or resident of the United States held an amount of ordinary shares that would represent 10% or more of the voting power of our Company.

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 U.S. dollar could cause our profits to decrease or our products to be less competitive against those of our competitors. To the extent that our foreign currency 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.

Current and changing economic conditions may adversely affect our industry, business, partners and suppliers, financial position, results of operations and/or cash flow.

The global economy continues to experience significant volatility, and the economic environment may continue to be, or become, less favorable than that of past years. Among other matters, the continued risk of a debt default by one or more European countries, related financial restructuring efforts in Europe, and/or evolving deficit and spending reduction programs instituted by the U.S. and other governments could negatively impact the global economy and/or the pharmaceutical industry. This has led, and/or could lead, to reduced consumer and customer spending and/or reduced or eliminated governmental or third party payor coverage or reimbursement in the foreseeable future, and this may include spending on healthcare, including but not limited to pharmaceutical products. While generic drugs present an alternative to higher-priced branded products, our sales could be negatively impacted if patients forego obtaining healthcare, patients and customers reduce spending or purchases, and/or if governments and/or third-party payors reduce or eliminate coverage or reimbursement amounts for pharmaceuticals and/or impose price or other controls adversely impacting the price or availability of pharmaceuticals. In addition, reduced consumer and customer spending, and/or reduced government and/or third party payor coverage or reimbursement, and/or new government controls, may drive us and our competitors to decrease prices and/or may reduce the ability of customers to pay and/or may result in reduced demand for our products. The occurrence of any of these risks could have a material adverse effect on our industry, business, financial position, results of operations and/or cash flow.

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. Any armed conflicts, terrorist activities or political instability in the region could 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.

Many male Israeli citizens, including our employees, are subject to compulsory annual reserve military service until they reach the age of 45 (or older, for citizens who hold certain positions in the Israeli armed forces reserves) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists, and some of our Israeli employees have been called up in connection with armed conflicts. It is possible that there will be similar large-scale military reserve duty call-ups in the future. 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 in Israel, primarily labor and occupancy expenses, are incurred in NIS. As a result, the cost of our operations in Israel, as measured in U.S. dollars, is subject to the risk of exchange rate fluctuations between the U.S. dollar and the NIS. During the year-ended March 31, 2018, the value of the NIS increased 3.3% with respect to the U.S. dollar. That change had a negative impact on our results of operations. If the NIS were to once again depreciate relative to the U.S. dollar, it would positively affect our U.S. dollar-measured results of operations. If the NIS were to appreciate ever further relative to the U.S. dollar, that would negatively affect

our U.S. 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 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 pricing or price control policies can materially impede our profitability or ability to set prices for our products.

The Israeli government typically purchases pharmaceutical products at the lowest prices in the market, which may affect our profitability. 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 Israeli government programs, including the Approved Enterprise program and programs of the National Technological Innovation Authority (the “Authority”) (formerly operating as Office of the Chief Scientist of the Ministry of Economy of the State of Israel). 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, 5759 - 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. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, a tender offer for all of a company’s issued and outstanding shares can only be completed if the acquirer receives sufficient responses such that the acquirer will hold at least 95% of the issued share capital upon consummation of the shareholders’ tenders. Completion of the tender offer also requires approval of a majority of shareholders who do not have a personal interest in the tender offer, unless, following consummation of the tender offer, the acquirer would hold at least 98% of the company’s outstanding shares. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition, unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights.

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.

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. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. With respect to other share swap transactions, the tax deferral is limited in time, and when this time expires, the tax becomes payable even if no disposition of the shares has occurred.

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. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws because Israel is not the most appropriate forum in which such a claim should be brought. Even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the applicable U.S. law must be proved as a factual matter, which can be a time-consuming and costly process. Also, certain matters of procedure will be governed by Israeli law.

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 threat to our business. Additionally, the substitution effect may adversely affect our ability to profitably market our products.

We may be adversely affected if the rate of inflation in Canada exceeds the rate of devaluation of the CAD against the U.S. dollar.

A substantial portion of our expenses, primarily labor, raw materials, occupancy, marketing and research and development expenses in Canada, are incurred in CAD. As a result, the cost of our operations in Canada, as measured in U.S. dollars, is subject to the risk of exchange rate fluctuations among the U.S. dollar and the CAD. During the year-ended March 31, 2018, the value of the CAD increased 3.0% with respect to the U.S. dollar. While that change

had a negative impact on our results of operations, if the CAD were to depreciate relative to the U.S. dollar, it would positively affect our U.S. dollar-measured results of operations. If the CAD were to appreciate ever further relative to the U.S. dollar, it would negatively affect our U.S. dollar-measured 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”). 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. In 2007, we sold 6,787,500 of our ordinary shares to Sun. In September 2010, the Levitt and Moros families and Sun Pharma reached an agreement to transfer their interest in Taro to Sun in accordance with an option agreement entered into by the parties in May 2007. Since March 22, 2012, our ordinary shares have been traded on the NYSE under the symbol “TARO.”

On December 23, 2013, the Company completed a modified “Dutch auction” tender offer through which the Company repurchased 1,959,514 ordinary shares at a price of \$97.50 per share.

On March 15, 2016, the Company announced that its Board of Directors approved a \$250 million share repurchase of ordinary shares, which was completed on August 18, 2016. Under the program, the Company bought back 1,801,099 of its ordinary shares in open market transactions, in accordance with a 10b5-1 program, at an average price of \$138.80 per share.

On November 23, 2016, the Company announced that its Board of Directors authorized a new \$250 million share repurchase of ordinary shares. Repurchases may be made from time to time at the Company’s discretion, based on ongoing assessments of the capital needs of the business, the market price of its stock, and general market conditions. No time period was set for the repurchase program, and any such program may be suspended or discontinued at any time. The repurchase authorization enables the Company to purchase its ordinary shares from time to time through open market purchases, negotiated transactions or other means, including 10b5-1 trading plans in accordance with applicable securities laws or other restrictions. On November 7, 2017, the Board extended the share repurchase program for one year. During the year ended March 31, 2018, the Company repurchased 1,085,694 shares through the current program at an average price of \$102.52. Through May 31, 2018, in total under the authorization, the Company has repurchased 1,806,984 shares at an average price of \$102.86, leaving \$64.1 million remaining under the current board authorization.

Our registered office is located at 14 Hakitor Street, Haifa Bay 2624761, 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 years ended March 31, 2018, 2017 and 2016, our capital expenditures were \$26.9 million, \$35.8 million and \$19.0 million, respectively. The focus of our capital expenditure program has been the expansion and upgrade of our manufacturing facilities, laboratories, 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 and serialization systems, in addition to general improvements to our facilities.

For a detailed presentation of our property, plant and equipment, see Note 7 to our consolidated financial statements included elsewhere in this 2018 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 Rx and OTC pharmaceutical products primarily in the United States, Canada and Israel. Our primary focus includes semi-solids formulations, such as creams and ointments and other dosage forms such as liquids, capsules and tablets, in the dermatological and topical, cardiovascular, neuropsychiatric and anti-inflammatory therapeutic categories.

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We operate principally through three entities: 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	<ul style="list-style-type: none"> • Manufactures more than 100 finished dosage form pharmaceutical products for sale in Israel and for export • 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 • Performs research and development 	<ul style="list-style-type: none"> • Dermatology: Rx and OTC semi-solid and liquid products (creams, ointments, lotions and gels) • Cardiology and Neurology: Prescription oral dosage products • Oral analgesics, Rx and OTC • Oral Central Nervous System (CNS) - Rx • OTC nasal sprays • Allergy (Antihistamine): OTC oral dosage products
Taro Canada	<ul style="list-style-type: none"> • Manufactures more than 200 finished dosage form pharmaceutical products for sale in Canada and for export • Markets and distributes both proprietary and generic products in the Canadian market • Performs research and development 	<ul style="list-style-type: none"> • Dermatology: Rx and OTC semi-solid products (creams, ointments and gels) and liquids • Allergy (Antihistamine): OTC oral dosage products
Taro U.S.A.	<ul style="list-style-type: none"> • Markets and distributes both proprietary and generic products in the U.S. market • Performs regulatory, post marketing and clinical activities 	<ul style="list-style-type: none"> • Dermatology: Rx and OTC semi-solid products (creams, ointments and gels) and liquids • Cardiology and Neurology: Rx oral dosage products • Other Rx and OTC products

As of March 31, 2018, 28 (excluding tentative approvals) of our ANDAs are being reviewed by the FDA. During the fiscal year ended March 31, 2018, we filed 7 ANDAs with the FDA. In addition, there are numerous 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.

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 200 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/Cosmetic
Acetaminophen	rectal suppository	Feverall®	Antipyretic	U.S.	OTC
Acetaminophen, Codeine and Caffeine	tablets	Rokacet®(2)	Analgesic	Israel	Rx/OTC
Acetazolamide	tablets	Diamox®	Carbonic anhydrase inhibitor	U.S., Israel	Rx
Acitretin	capsules	Soriatane®	Dermatologics	Canada	Rx
Acyclovir	ointment	Zovirax®	Dermatologics and topicals	U.S.	Rx
Adapalene	gel	Differin®	Dermatologics and topicals	U.S.	Rx
Adapalene & Benzoyl Peroxide	gel	Epiduo®	Dermatologics and topicals	U.S.	Rx
Alclometasone Dipropionate	cream, ointment	Aclovate®	Dermatologics and topicals	U.S.	Rx
Alnase	solution	Pyrilamine®	Allergy	Israel	OTC
Amcinonide	cream	Cyclocort®	Dermatologics and topicals	Canada	Rx
Amiodarone Hydrochloride	tablets	Cordarone®	Cardiovascular	U.S.	Rx
Ammonium Lactate	cream, lotion	Lac-Hydrin®	Dermatologics and topicals	U.S., Canada	Rx/OTC
Anastrozole	tablets	Arimidex®	Nonsteroidal aromatase inhibitor	Canada	Rx
Augmented Betamethasone Dipropionate	cream, lotion, gel	Diprolene AF®	Dermatologics and topicals	U.S.	Rx
Bacitracin	ointment	Baciquent®	Dermatologics and topicals	U.S.	OTC
Benzoyl Peroxide & Clindamycin Phosphate	gel	Duac®	Dermatologics and topicals	U.S.	Rx
Benzoyl Peroxide/Clindamycin	gel kit	Benzaclin®	Dermatologics and topicals	Canada	Rx
Betamethasone Dipropionate	cream	Diprosone®	Dermatologics and topicals	U.S., Canada	Rx
Betamethasone Valerate	cream, topical foam	Valisone®	Dermatologics and topicals	U.S., Canada	Rx
Brexin	tablets		Anti-Inflammatory & Analgesic	Israel	Rx
Brompheniramine Maleate, Pseudoephedrine Hydrochloride,	syrup	Bromfed-DM®	Allergy	U.S.	Rx

Dextromethorphan Hydrobromide					
Butamine	solution for infusion	Dobutrex®	Cardiovascular	Israel	Rx
Butenafine Hydrochloride	cream	Lotrimin Ultra®	Dermatologics and topicals	U.S.	OTC
Calcimore	chewable tablets	Calcimore®	Gastrointestinal	Israel	Rx
Calcipotriene	ointment	Dovonex®	Dermatologics and topicals	U.S.	Rx
Capecitabine	tablets	Xeloda®	Antineoplastics	Canada	Rx
Carbamazepine	tablets, controlled release tablets, chewable tablets, oral suspension	Tegretol®	Anticonvulsant	U.S., Israel, Canada	Rx
Cetirizine Hydrochloride	solution	Zyrtec®	Allergy	U.S.	Rx/OTC
Ciclopirox	shampoo	Penlac®	Dermatologics and topicals / Antifungal	U.S., Canada	Rx
Ciclopirox Olamine	cream, topical solution	Loprox®	Dermatologics and topicals / Antifungal	U.S.	Rx
Clarithromycin	suspension	Biaxin®	Antibiotic	Canada	Rx
Clindamycin Phosphate	topical solution	Cleocin T®	Dermatologics and topicals	U.S., Canada	Rx
Clindamycin/Benzoyl Peroxide	gel	Clindoxyl®	Dermatologics and topicals	Canada	Rx

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Clobetasol Propionate	cream, ointment, gel, topical solution, lotion	Temovate® , Clobex®	Dermatologics and topicals	U.S., Canada	Rx
Clomipramine Hydrochloride	capsule	Anafranil®	Neuropsychiatric	U.S.	Rx
Clorazepate Dipotassium	tablets	Tranxene®	Neuropsychiatric	U.S.	Rx
Clotrimazole and Betamethasone Dipropionate	cream, lotion	Lotrisone®	Dermatologics and topicals / Antifungal	U.S., Israel	Rx
Clotrimazole	cream, topical solution, vaginal cream	Lotrimin®	Dermatologics and topicals / Antifungal	U.S., Canada	Rx/OTC
Clotrimazole/Fluconazole	cream/capsule	Gyne-Lotrimin® CanesOral®	Dermatologics and topicals/antifungal	Canada	OTC
Curatane	capsule	Accutane®	Dermatologics and topicals	Israel	Rx
Dapsone	gel	Aczone®	Dermatologics and topicals	U.S.	Rx
Deferasirox	dispersible tablets	Exjade®	Iron chelating agent	Canada	Rx
Dermacombin	cream	Dermacombin®	Dermatologics and topicals / Antifungal	Israel	Rx
Desonide	cream, ointment, lotion	Tridesilon® , Des-Owen®	Dermatologics and topicals	U.S.	Rx
Desoximetasone	cream, ointment, gel, spray	Topicort®(2)	Dermatologics and topicals	U.S.	Rx
Diclofenac Sodium	solution, gel	Pennsaid®, Solaraze®	Dermatologics and topicals	U.S., Canada	Rx
Diflorasone Diacetate	cream, ointment	Psorcon®	Dermatologics and topicals	U.S.	Rx
Diphenhydramine	cream	Benadryl®	Dermatologics and topicals	U.S.	OTC
Diprolol	emulsion for injection or infusion	Diprivan®	Sedative/hypnotic	Israel	Rx
Docusate Sodium	gel capsules	Soflax®	Gastrointestinal	Canada	OTC
Dorzolomid + Timolol	drops	Colace® Cosopt®	Intraocular pressure	Israel	Rx
Double Antibiotic	ointment	Polysporin®	Dermatologics and topicals	Canada	OTC
Econazole Nitrate	cream	Spectazole®	Dermatologics and topicals / Antifungal	U.S.	Rx
Enalapril Maleate	tablets	Vasotec®	Cardiovascular	U.S.	Rx
Enalapril Maleate / Hydrochlorothiazide	tablets	Vaseretic®	Cardiovascular	U.S.	Rx
Entumin	tablets	Entumin®	Neuropsychiatric	Israel	Rx
Estelle	tablets	Androcur®	Endocrine	Israel	Rx
Etodolac	tablets, capsules, extended release tablets	Etopan®(2) Lodine®	Anti-Inflammatory & Analgesic	U.S., Israel	Rx
Felbamate	tablets, suspension	Felbatol®	Anticonvulsant	U.S.	Rx
Fluocinolone Acetonide	solution, oil	Synalar®, Derma-Smooth®	Dermatologics and topicals	U.S.	Rx

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Fluocinonide	cream, ointment, gel, topical solution	Lidex®, Vanos®	Dermatologics and topicals	U.S., Canada	Rx
Fluorouracil	topical solution, cream	Efudex®	Topical Anti-neoplastic	U.S.	Rx
Flurandrenolide	cream, lotion	Cordran®	Dermatologics and topicals	U.S.	Rx
Hydrocortisone 1% and Acetic Acid 2%	solution	Vosol HC Otic®	Antibacterial	U.S.	Rx
Hydrocortisone Butyrate	cream, ointment, topical solution	Locoid®	Dermatologics and topicals	U.S.	Rx
Hydrocortisone Valerate	cream, ointment	Westcort®	Dermatologics and topicals	U.S., Canada	Rx
Hydrocortisone	cream, ointment	Cortizone 10®, Hytone®	Dermatologics and topicals	U.S., Canada	Rx/OTC
Imiquimod	cream	Aldara®	Dermatological and topical	U.S.	Rx

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Jungborn	granules	Jungborn®	Laxative	Israel
Ketoconazole	tablets, cream	Nizoral®	Dermatologics and topicals / Antifungal	U.S., Canada
Lamotrigine	tablets	Lamictal®	Anticonvulsant	U.S.
Levocetirizine Dihydrochloride	solution	Xyzal®	Allergy	U.S.
Lidocaine	ointment	Xylocaine™	Dermatologics and topicals	U.S.
Lidocaine / Tetracaine	gel	Pliaglis®	Dermatologics and topicals	U.S.
Loratadine	solution	Claritin®	Allergy	U.S., Canada
Lozapine	tablets	Clozaril®	Neuropsychiatric	Israel
Macrogols, Potassium chloride, Sodium Bicarbonate, Sodium chloride	powder for solution	Meroken™(2)	Laxative	Israel
Malathion	lotion	Ovide®(2)	Dermatologics and topicals	U.S.
Mercaptizol	tablets	Tapazole®	Endocrine	Israel
Metronidazole	gel	MetroGel®	Dermatologics and topicals	U.S.
Miconazole Nitrate	vaginal cream, cream	Monistat® 3 Monistat® 7 Micatin®	Dermatologics and topicals / Antifungal	U.S., Canada
Mometasone Furoate	lotion, cream	Elocon®	Dermatologics and topicals	Canada
Mupirocin	ointment	Bactroban®	Dermatologics and topicals	U.S., Canada
Naftifine HCL	cream	Naftin®	Dermatologics and topicals / Antifungal	U.S.
Nexium	tablets	Nexium®	Gastrointestinal	Israel
Normalax	powder	Miralax®	Gastrointestinal	Israel
Nortriptyline	capsule	Pamelor®	Neuropsychiatric	U.S.
Nystatin	cream	Mycostatin®	Antifungal Oral and topical	U.S., Israel, Canada
Nystatin/Triamcinolone	cream, ointment	Mycogen® II, Mycolog® II, Myconel®	Dermatologics and topicals / Antifungal	U.S.
Nystatin/Triamcinolone/Neomycin/Gramicidin	cream, ointment	Kenacomb®	Dermatologics and topicals / Antifungal/antibiotic	Canada
Ondansetron	solution	Zofran®	Antiemetic	U.S.
Oracort E	paste	Xylocaine and lignocaine®	Dermatologics and topicals	Israel
Otomycin	drops	Otomycin®	Antibacterial	Israel
Oxacatin	syrup	Oxacatin®	Cough & Cold	Israel
Oxaliplatin	injectable	Eloxatin®	Antineoplastics	Canada
Oxiconazole Nitrate	cream	Oxistat®	Dermatologics and topicals / Antifungal	U.S.
Partane	tablets	Benzhexol and trihex®	CNS	Israel
Pemetrexed Disodium	injectable	Alimta®	Antineoplastics	Canada
Percocet	tablets	Percocet®	Narcotics	Israel
Perphenan	tablets	Perphenan®	Neuropsychiatric	Israel

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Phenytoin Sodium	extended release capsules, chewable tablets, suspension	Dilantin®	Anticonvulsant	U.S., Canada
Pregabalin	tablets	Lyrica®	Neuropathic pain	Israel
Profex	tablets	Rythmol SR®	Cardiovascular	Israel
Promethazine	rectal suppository	Phenergan®	Allergy & Antiemetic	U.S.
Promnix	modified release capsules	Alna ® / Flomax ®	Endocrine	Israel
Ridazin	tablets	Melleril®	Neuropsychiatric	Israel
Sebosel	suspension	Sebosel®	Dermatologics and topicals	Israel
Sevelamer	tablets	Renvela®	Control of Hyper phosphataemia	Israel
Sterocort	tablets	Sterocort®	Corticosteroid	Israel
Sumatriptan Succinate	injectable	Imitrex®	CNS	Canada
Taro Base	cream	Glaxal® base	Dermatologics and topicals	Canada
Taro Gel	gel	K-Y® gel	Dermatologics and topicals/lubricant	Canada

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Tarodent	solution	Tarodent®	Anti-infectives for local oral	Israel	OTC
Tazarotene	cream	Tazorac®	Dermatologics and topicals	U.S.	Rx
Temozolomide	capsules	Temodal®	Antineoplastics	Canada	Rx
Terbinafine Hydrochloride	cream	Lamisil®	Dermatologics and topicals / Antifungal	U.S.	OTC
Terconazole	vaginal cream	Terazol®	Dermatologics and topicals / Antifungal	U.S., Canada	Rx
Testosterone Undecanoate	gel capsules	Andriol®	Endocrine	Canada	Rx
Tolnaftate	cream	Tinactin®	Dermatologics and topicals / Antifungal	U.S., Canada	OTC
Tramadol Hydrochloride	extended release tablets	Tridural®	Analgesic	Canada	Rx
Triamcinolone Acetonide	cream, ointment, dental paste	Kenalog®	Dermatologics and topicals	U.S., Canada, Israel	Rx
Triple Antibiotic	ointment	Neosporin®	Dermatologics and topicals	U.S., Canada	OTC
Warfarin Sodium	tablets	Coumadin®	Cardiovascular	U.S., Israel, Canada	Rx
Zindaclin	gel	Zindaclyn®	Dermatologics and topicals	Israel	Rx
Zoledronic acid	injectable	Aclasta®	Bone metabolism regulator	Canada	Rx
		Zometa®			
N/A	shampoo & spray	Pilexil®	Cosmetic	Israel	Cosmetic
N/A	toothpaste & mouthwash	Lacer®	Cosmetic	Israel	Cosmetic

(1) Presented in this column are the brand-names under which the products are most commonly prescribed in the United States. Except as noted below, we do not own any of the specific names. In some cases, we manufacture and sell the generic equivalent of the product sold by the third-party owner of such name. For example, we sell our product warfarin sodium tablets under that name in the United States. Warfarin sodium is the generic equivalent of Coumadin, a product sold under that name in the United States by the third-party owner of the United States rights to that name and by us in Israel, where we own the right to use that name.

(2) Taro brands.

Topical corticosteroids are used in the treatment of some dermatologic conditions (including psoriasis, eczema and various types of skin rashes). Topical antineoplastics are used in the treatment of cancer (including skin cancer). Antifungals are used in the treatment of some infections (including athlete's foot, ringworm and vaginal yeast infections). Anticonvulsants are used in the treatment of various seizure disorders (including epilepsy). Cardiovascular products are used in the treatment of heart disease. There are several categories of cardiovascular drugs, including anticoagulants, antihypertensive and antiarrhythmic. Anticoagulants, commonly known as blood thinners, are used in the treatment of heart disease and stroke associated with heart disease.

Some of our products are subject to seasonality, such as allergy drugs, however, in the aggregate our products are not materially subject to seasonality.

Sales and Marketing

In the United States, Israel and Canada, our sales are primarily generated by our own dedicated sales force. In other countries, we sell through agents and other distributors. Our sales force is supported by our customer service and marketing employees.

The following is a breakdown of our net sales by geographic region, including the percentage of our total consolidated net sales for each period:

	Year ended March 31,		2017		2016	
	2018		2017		2016	
	Sales	% of	Sales	% of	Sales	% of
	(in thousands of total sales)		(in thousands of total sales)		(in thousands of total sales)	
United States	\$549,174	83	% \$785,319	89	% \$865,224	91
Canada	67,226	10	% 57,621	7	% 56,605	6
Israel	38,223	6	% 29,200	3	% 22,963	2
Other	7,290	1	% 7,247	1	% 5,959	1
Total	\$661,913	100	% \$879,387	100	% \$950,751	100

In the year ended March 31, 2018, revenue in the United States accounted for 83% of total consolidated net sales. In addition to marketing Rx drugs, we market our generic OTC products primarily as store brands under its customers' labels to wholesalers, drug chains, food chains and mass merchandisers. During the year ended March 31, 2018, we sold to approximately 130 customers in the United States. The following table represents sales to our three largest customers as a percent of consolidated net sales:

Customer	Year ended March 31,		
	2018	2017	2016
Customer A	15.3%	14.2%	14.1%
Customer B	11.5%	10.3%	14.0%
Customer C	11.4%	19.3%	20.0%

The following table sets forth the percentage of consolidated net sales by each type of customer in the United States in the year ended March 31, 2018:

Customer Type	Percentage of Consolidated Sales
Drug wholesalers and store chains	48%
Mass merchandisers, food and retail chains	16%
Managed care organizations	9%
Generic drug distributors	6%
Other	4%

In the year ended March 31, 2018, sales in Canada accounted for 10% of our total consolidated net sales and Taro Canada sold to approximately 45 customers.

The PMPRB monitors and controls prices of patented drug products marketed in Canada by persons holding, or licensed under, one or more patents. The existence of one or more patents relating to a drug product triggers a governmental price control regime that significantly affects the Canadian pharmaceutical industry's ability to set pricing. Furthermore, 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. Provincial governments generally will reimburse the lowest available price of the generic equivalents of any drug listed on the formulary list of a province. Consequently, provincial formulary regimes tend to encourage the sale of lower-priced versions of pharmaceutical products.

The following table sets forth the percentage of consolidated net sales by each type of customer in Canada in the year ended March 31, 2018:

Customer Type	Percentage of Consolidated Sales	
Drug wholesalers	7	%
Drug chains, independent pharmacies and others	3	%

In the year ended March 31, 2018, sales in Israel accounted for 6% of our total consolidated net sales. The marketing, sales and distribution of Rx pharmaceuticals and OTC products in Israel is closely monitored by the Israeli government. The market for these products is dominated by institutions that are similar to health maintenance organizations in the United States, as well as private pharmacies. Most of our marketing efforts in Israel focus on selling directly to these groups.

All pharmaceutical products sold in Israel are subject to price controls. Permitted price increases and decreases are enacted by the Israeli government as part of a formal review process. There are no restrictions on the import of pharmaceuticals, provided that they comply with registration requirements of the Israeli Ministry of Health.

In Israel, the pharmaceutical market generally is divided into two market segments: (i) the private market, which includes drug store chains, private pharmacies and wholesalers; and (ii) the institutional market, which includes Kupat Holim Clalit (the largest health maintenance organization in Israel), other health maintenance organizations, the Israel Ministry of Health, the Armed Forces, and sales to the Palestinian authorities through third parties.

The following table sets forth the percentage of consolidated net sales by each type of customer in Israel and other international markets in the year ended March 31, 2018:

Customer Type	Percentage of Consolidated Sales	
Institutional	2	%
Private	4	%
Other international	1	%

We have expanded the production capacity of our Israeli and Canadian operations to meet anticipated greater demand for our products in future years. As discussed below under “Industry Practice Relating to Working Capital Items,” future demand for our products may not increase at a rate we previously anticipated. In addition, we utilize contract manufacturers for certain products to satisfy customer demand in a timely manner. As a result, in each of the years ended March 31, 2018, 2017 and 2016, backorders represented less than 5% of our consolidated net sales.

Competition and Pricing

The pharmaceutical industry is intensely competitive. We compete with the original manufacturers of the brand-name equivalents of our generic products, other generic drug manufacturers (including brand-name companies that also manufacture generic drugs or license their products to other generic drug manufacturers) and manufacturers of new drugs that may compete with our generic drugs. Many of our competitors have greater financial, production and research and development resources, substantially larger sales and marketing organizations, and substantially greater name recognition than we have. In the recent past, the barriers to entry for new entrants to the generic industry have significantly reduced, thus resulting in a larger competitive field. At the same time, the customer base for the generic manufacturers has seen significant consolidation at the purchasing level, resulting in increased purchasing power for the customer. This dual effect of increased competition and increased purchasing power has resulted in a downward trend for prices for our generic products.

Additionally, brand-name drug companies have historically attempted to prevent generic drug manufacturers from producing certain products and to prevent competing generic drug products from being accepted as equivalent to their brand-name products. We expect such efforts to continue in the future. Also, some brand-name competitors, in an attempt to participate in the generic drug sales of their branded products, have introduced generic equivalents of their own branded products, both prior and subsequent to the expiration of their patents or FDA exclusivity periods for such drugs. These competitors have also introduced authorized generics or generic equivalents of brand-name drug products. Our brand-name drug competitors are increasingly selling their branded products through controlled distribution channels, further limiting our access and increasing competitive intensity with those generic manufacturers.

Competitive factors in the major markets in which we participate can be summarized as follows:

North America

The U.S. pharmaceutical market is undergoing, and is expected to continue to undergo, rapid and significant market and technological changes and we expect competition to intensify as these market and scientific advances are made. We intend to effectively compete in this marketplace by focusing on a niche product development strategy highlighted by differentiated technologies and dedicated focus on therapeutic areas which play to our strengths.

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In the United States, we compete with branded pharmaceutical manufacturers such as Bristol-Myers Squibb Company, Celgene Corporation, GlaxoSmithKline Inc., Merck & Co., Inc., Novartis AG, Pfizer Inc., Valeant Pharmaceuticals International, Inc. and Galderma Laboratories, LP., as well as with generic companies such as Teva Pharmaceuticals U.S.A., Mylan Inc., Perrigo Company PLC, Glenmark Generics, Inc., USA and Sandoz Pharmaceuticals (the generics subsidiary of Novartis). Many of these companies have more resources, market and name recognition and better access to customers than we have. Therefore, there can be no assurance that we can compete successfully with them.

A significant portion of our sales are made to a relatively small number of wholesalers, retail drug chains, food chains and mass merchandisers, which continue to undergo significant consolidation. We face increasing product pricing pressures as a result of this consolidation as well as the emergence of large buying groups who are able to negotiate price discounts on our products.

There can be no guarantee that Taro will not continue to experience challenges during the current year in comparison to prior years, especially for our generic drug division, due to price erosion from our customers increased focus on lower pricing, customer consolidation and increased competition in specific product segments due to new entrants in our markets. These challenges could have a material impact on our business, cash flows, and results of operations or result in impairment charges, and the market value of our share price may decline.

Canada

In Canada, our competition includes Merck Canada Inc., Pfizer Canada Inc., Janssen Inc., Novartis Pharmaceuticals Canada Inc., GlaxoSmithKline Inc., Valeant Canada, AstraZeneca Canada, Johnson & Johnson Inc., Bayer Inc. and Bristol-Myers Squibb Canada. We also compete with other manufacturers of generic products, such as Apotex Inc., Teva Canada Limited, Mylan Pharmaceuticals ULC, Sandoz Canada Incorporated and Pharmascience Inc.

Depending on the product, pricing in Canada is established by competitive factors or by Canadian provincial formulary price lists published by the Canadian provinces.

Israel

In Israel, we compete with Teva Pharmaceutical Industries Ltd., Perrigo Israel Pharmaceuticals Ltd., Dexcel Pharma Israel, and Rafa Laboratories Ltd., among others. In addition, many leading multinational companies, including Bayer AG, Eli Lilly and Company, Merck & Co., Inc. and Pfizer Inc. market their products in Israel.

In Israel, the government establishes the prices for pharmaceutical products as part of a formal review process. There are no restrictions on the import of pharmaceuticals provided that they comply with registration requirements of the Israeli Ministry of Health.

Manufacturing and Raw Materials

We currently manufacture finished pharmaceutical products at our government approved facilities in Canada and Israel and APIs in our Israel facility.

For the manufacture of our finished dosage form pharmaceutical products, we use pharmaceutical chemicals that we either produce ourselves or purchase from chemical manufacturers in the open market globally. Substantially all of such chemicals are obtainable from a number of sources, subject to regulatory approval. However, we purchase certain raw materials from single source suppliers. The decision to purchase APIs is a function of our sales forecast and prevailing prices in the market. When appropriate purchasing opportunities arise, the Company may acquire certain APIs in excess of its ordinary requirements or rate of growth. Obtaining the regulatory approvals required to add alternative suppliers of such raw materials for products sold in the United States or Canada 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 such regulatory approvals will not have a material adverse effect on our business. However, we may become unable to sell certain products in the United States, Canada, or Israel pending approval of one or more alternate sources of raw materials.

We synthesize the APIs used in some of our key products, including our warfarin sodium tablets, carbamazepine products, etodolac tablets, terbinafine cream, imiquimod cream, fluocinonide cream, naftifine cream, oxiconazole nitrate cream, lamotrigine tablets, clorazepate dipotassium tablets, cetirizine oral solution and desoximetasone spray. We plan to continue the strategic selection of APIs for synthesis in order to maximize the advantages from this scientific and manufacturing capability.

Although, prices of principal raw materials have been relatively stable, the Company has programs to keep the cost of APIs consistent or to improve upon them; for example, through the qualification of alternate suppliers and process improvements.

Industry Practices Relating to Working Capital Items

Certain customary industry selling practices affect our working capital, including, but not limited to, providing favorable payment terms to customers and discounting selling prices through the issuance of free products as well as other incentives within a specified time frame if a customer purchases more than a specified threshold of a product. These incentives are provided principally with the intention of maintaining or expanding our distribution to the detriment of competing products.

Industry practice requires that pharmaceutical products be made available to customers from existing stock rather than on a made-to-order basis. Therefore, in order to accommodate market demand adequately, we strive to maintain a sufficient level of inventory.

Government Regulation

We are subject to extensive pharmaceutical industry regulations in the United States, Canada, Israel and other jurisdictions, and may be subject to future legislative and other regulatory developments concerning our products and the healthcare field generally. Any failure by us to comply with applicable policies and regulations of any of the numerous authorities that regulate our industry could have a material adverse effect on our results of operations.

In the United States, the Federal Food, Drug, and Cosmetic Act (the "FDC Act") and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications ("NDAs"), warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. In Canada, Israel and other jurisdictions, the manufacture and sale of pharmaceutical products are regulated in a similar manner. Legal requirements generally prohibit the handling, manufacture, marketing and importation of any pharmaceutical product unless it is properly registered in accordance with applicable law. In addition, approval is required before any new drug or a generic equivalent to a previously approved drug can be marketed. Furthermore, each country requires successful inspections or approval of manufacturing facilities, including adherence to cGMPs during the production and storage of pharmaceutical components, including, but not limited to, raw materials and finished products. As a result, we have had periodic inspections of our facilities and records.

Regulatory authorities in each country also have extensive enforcement powers over the activities of pharmaceutical manufacturers, including the power to seize, force the recall of and prohibit the sale or import of non-complying products and to halt the operations of and criminally prosecute and fine non-complying manufacturers. These regulatory authorities also have the power to revoke approvals previously granted and remove from the market previously approved drug products.

In the United States, Canada, Israel and other jurisdictions, we, as well as other manufacturers of drugs, are dependent on obtaining timely approvals for products. The approval process in each country has become more rigorous and costly in recent years. There can be no assurance that approvals will be granted in a timely manner or at all. In the United States, Canada, Israel and other jurisdictions, the procedure for drug product approvals, if such approval is ultimately granted, generally takes longer than one year. The review processes in Canada and Israel are substantively similar to the review process in the United States.

In the United States, any drug that is not generally recognized as safe and effective by qualified experts for its intended use is deemed to be a new drug, which generally requires FDA approval. Approval is obtained, either by the submission of an ANDA or an NDA. If the new drug is a new dosage form, a strength not previously approved, a new indication or an indication for which the ANDA procedure is not available, an NDA is required. Pharmaceutical

product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application (“IND”), which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA approval to market requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice (“GCP”), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (“IRB”), for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions.

We generally receive approval for generic products by submitting an ANDA to the FDA. An ANDA provides for marketing of a drug product that contains the same active ingredient and has the same route of administration, dosage form, and strength as a previously approved drug (also known as the reference listed drug) and has been shown to be bioequivalent to the reference listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical tests to prove the safety or effectiveness of their drug product. Bioavailability is generally determined by the rate and extent of absorption and levels of concentration of a drug product in the blood stream needed to produce a therapeutic effect. Bioequivalence compares the bioavailability of one drug product with another and, when established, indicates that the rate of absorption and levels of concentration of a generic drug in the body or on the skin are substantially equivalent to the previously approved brand-name reference listed drug. ANDA approvals are granted after the review by the FDA of detailed information submitted as part of the ANDA regarding the pharmaceutical ingredients, drug production methods, quality control, labeling, and demonstration that the product is bioequivalent to the brand-name reference listed drug. Demonstrating bioequivalence generally requires data demonstrating that the generic formula results in a product whose rate and extent of absorption are within an acceptable range of the results achieved by the brand-name reference listed drug. In some instances, bioequivalence can be established by demonstrating that the therapeutic effect of the generic product falls within an acceptable range of the therapeutic effects achieved by the brand-name reference listed drug. Generic drug user fees pursuant to the Generic Drug User Fee Amendments must be paid to FDA upon submission of each ANDA and Drug Master Files as well as for any manufacturing facilities. In addition, an applicant under an approved ANDA is subject to an annual program fee based on the number of ANDAs held.

Products resulting from our proprietary drug program may require us to submit an NDA to the FDA. An NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product’s pharmacology, chemistry, manufacture, and controls. The clinical studies required prior to the NDA submission are both costly and time consuming, and often take five to seven years or longer, depending, among other factors, on the nature of the chemical ingredients involved and the indication for which the approval is sought. The cost of preparing and submitting an NDA is also substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the applicant under an approved NDA is also subject to an annual program fee for each prescription drug product pursuant to the Prescription Drug User Fee Act. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency’s threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. A majority of such applications for standard review drug products are reviewed within 10 to 12 months; most applications for

priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for drugs intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

Among the requirements for drug approval by the FDA is that manufacturing procedures and operations conform to cGMP. The cGMP regulations must be followed at all times during the manufacture of pharmaceutical products. During the review of an NDA or ANDA, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. If the FDA believes a company is not in compliance with cGMP, certain sanctions may be imposed, including: (i) withholding new drug approvals as well as approvals for supplemental changes to existing applications; (ii) preventing the receipt of necessary licenses to export products; (iii) preventing the importation of certain products into the United States; (iv) classifying the company as an unacceptable supplier and thereby disqualifying the company from selling products to federal agencies; and (v) pursuing a consent decree or court action that limits company operations and/or imposes monetary fines.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

As a condition of ANDA or NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS"), to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

In addition, because we market a controlled substance in the United States and other controlled substances in Canada and Israel, we must meet the requirements of the federal Controlled Substances Act and relevant state laws and regulations in the United States as well as equivalent laws in Canada and Israel. These regulations include stringent requirements for registration, manufacturing controls, receipt and handling procedures, recordkeeping and reporting and security to ensure accountability and prevent diversion of, or the unauthorized access to, the controlled substances in each stage of the production, storage and distribution process. The DEA inspects manufacturers, distributors, importers, and exporters to review compliance with the Controlled Substances Act and DEA regulations including security, record keeping and reporting prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled by the registrant. Once registered, manufacturing, distribution, exporting or importing facilities must maintain records documenting the manufacture, receipt, distribution, import, or export of all controlled substances. Manufacturers are required to obtain quotas for certain Schedule I and II controlled substances. Also, manufacturers and distributors must submit periodic reports to the DEA on the distribution of Schedule I and II controlled substances, Schedule III

narcotic substances, and other designated substances. All DEA registrants must report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. In addition to maintaining an importer and/or exporter registration, importers and exporters of controlled substances must obtain a permit for every import or export of a Schedule I or II substance and a narcotic substance in Schedule III, IV and V. For all other drugs in Schedule III, IV and V, importers and exporters must submit an import or export declaration. Failure to maintain the appropriate registrations or to obtain sufficient quota or approval for imports and exports could have a material adverse effect on our business. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

In May 1992, the Generic Drug Enforcement Act of 1992 (the “Generic Act”) was enacted. The Generic Act, a result of legislative hearings and investigations into the generic drug approval process, allows the FDA to impose debarment and other penalties on individuals and companies that commit certain illegal acts relating to the generic drug approval process. In some situations, the Generic Act requires the FDA not to accept or review, for a period of time, ANDAs from a company or an individual that has committed certain violations. It also provides for temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, provides for the suspension of the marketing of approved drugs by the affected company.

The Generic Act also allows for civil penalties and withdrawal of previously approved applications. To our knowledge, neither we nor any of our employees has ever been subject to debarment.

Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act (“PDMA”), a part of the FDC Act. In addition, Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act (“DSCSA”), has imposed new “track and trace” requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. These requirements are being phased in over a ten-year period. The DSCSA ultimately will require product identifiers (i.e., serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. These requirements will result in increased expenses and may create additional administrative encumbrances. Failing to comply with these requirements could result in penalties or fines.

Several types of state and federal laws have been applied to prohibit or restrict certain marketing practices in the pharmaceutical industry. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The PPACA, enacted in March 2010, amended the intent element of the federal anti-kickback statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties, and/or exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

The Federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement material to a false claim. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Numerous pharmaceutical companies have been sued under this law for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates. In addition, certain marketing practices, including off-label promotion, may also violate the Federal False Claims Act. Additionally, the PPACA amended the federal anti-kickback statute such that a violation of that statute can also serve as a basis for liability under the Federal False Claims Act. The majority of states also have statutes or regulations similar to the federal anti-kickback law and the Federal False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

There are also an increasing number of state laws with requirements for manufacturers and/or marketers of pharmaceutical products. Some states require the reporting of expenses relating to the marketing and promotion of drug products and the reporting of gifts and payments to individual healthcare practitioners in these states. Other

states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the reporting of certain pricing information, including information pertaining to and justification of price increases greater than a specified threshold, or prohibit prescription drug price gouging. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us, and companies that do not comply with these state laws face civil penalties.

Federal law requires that a pharmaceutical manufacturer, as a condition of having its products receive federal reimbursement under Medicaid and Medicare Part B, must pay rebates to state Medicaid programs for all units of its covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under either a fee-for-service arrangement or through a managed care organization. The rebates are based on prices reported to CMS by manufacturers for their covered outpatient drugs (AMP for generic drugs, and AMP and best price for brand drugs). CMS issued final regulations regarding the calculation of AMP and rebates under the Medicaid Drug Rebate Program, effective as of April 1, 2016. The terms of participation in the Medicaid Drug Rebate Program impose an obligation to correct the prices reported in previous quarters, as may be necessary. Any such corrections could result in additional or lesser rebate liability, depending on the direction of the correction. In addition to retroactive rebates, if a manufacturer were found to have knowingly submitted false information to the government, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

A manufacturer must also participate in a federal program known as the 340B drug pricing program in order for federal funds to be available to pay for the manufacturer's drugs under Medicaid and Medicare Part B. Under this program, the participating manufacturer agrees to charge certain safety net healthcare providers no more than an established discounted price for its covered outpatient drugs. The formula for determining the discounted price is defined by statute and is based on the AMP and the unit rebate amount as calculated under the Medicaid Drug Rebate Program, discussed above.

Federal law also requires that manufacturers report data on a quarterly basis to CMS regarding the pricing of drugs that are separately reimbursable under Medicare Part B. These are generally drugs, such as injectable products, that are administered "incident to" a physician service and are not generally self-administered, as well as certain vaccines and oral dosage form chemotherapy and immunosuppressive therapy drugs. The pricing information submitted by manufacturers is the basis for reimbursement to physicians and suppliers for drugs covered under Medicare Part B. As with the Medicaid Drug Rebate Program, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

Manufacturers are also required to make their covered drugs, which are generally drugs approved under NDAs or biologics license applications ("BLAs"), available to authorized users of the Federal Supply Schedule ("FSS") of the General Services Administration. The law also requires manufacturers to offer discounted FSS contract pricing for purchases of their covered drugs by certain government agencies in order for federal funding to be available for reimbursement or purchase of the manufacturer's drugs under certain federal programs. The discounts are determined based on prices that are calculated and reported to the government by manufacturers. The accuracy of a manufacturer's reported prices may be audited by the government. Among the remedies available to the government for inaccuracies is recoupment of any overcharges to the government. If a manufacturer were found to have knowingly reported false prices, in addition to other penalties available to the government, the law provides for civil monetary penalties per incorrect item.

The PPACA, as well as subsequent legislation, such as the BBA, has had an impact on all segments of the health care industry. Pharmaceutical and medical device manufacturers have seen an increase in revenues by virtue of additional Americans who have access to health insurance beginning in 2014; however, the legislation imposes on manufacturers a variety of additional rebates, discounts and fees that have curtailed that increase in revenues. For example, Medicare Part D beneficiaries within the coverage gap receive a manufacturer funded, 50% point-of-sale discount (in 2017) off of negotiated prices for brand drugs (approved via an NDA or BLA). The Bipartisan Budget Act of 2018 increased the manufacturer's subsidy under the program from 50% to 70% of the negotiated price, beginning in 2019. As another example, the PPACA increased the minimum Medicaid rebate rate from 15.1% to 23.1% of AMP for most drugs approved under an NDA, and increased the Medicaid rebate from 11% to 13% of AMP for drugs approved under an ANDA. In another example, under the BBA, generic drugs approved under an ANDA are subject to an additional Medicaid rebate if the AMP for a given quarter exceeds the inflation-adjusted baseline AMP, effective for the first calendar quarter of 2017. This price increase penalty previously applied only to innovator drugs. For generic

drugs, the baseline AMP will depend on when the drug was launched. For innovator drugs, the baseline AMP is the AMP for the first full quarter after launch. Also, annual fees are imposed on each manufacturer and importer of branded prescription drugs or biologics, based on the ratio of its sales reimbursed or purchased by government agencies to such sales made by all drug manufacturers during the prior year, and based on different sales dollar tiers (the highest being over \$400 million in brand sales, and the lowest being at least \$5 million in brand sales).

The PPACA also imposed reporting and regulatory requirements. For example, the “sunshine” provisions impose reporting requirements and public disclosure requirements on a drug manufacturer’s payments to physicians and teaching hospitals, and on drug sample distributions. Annual reports are due in March of each year. The data reported under the “sunshine” provisions are posted in searchable form on a public website.

In addition, the legislation advances the policy of comparative clinical effectiveness research on medical treatments, services and items, including drugs and devices. Taken together, these government-adopted health care reform measures may adversely impact the pricing of healthcare products and services in the United States and the amount of reimbursement available from governmental agencies or other third-party payors. Government cost control initiatives could decrease the price that we or any current or potential collaborators could receive for any of our products and could adversely affect our profitability.

Environmental Compliance

We believe that we are currently in compliance with all applicable environmental laws and regulations in all of the countries in which we operate.

C. ORGANIZATIONAL STRUCTURE

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.

The following is a list of our significant subsidiaries and their countries of incorporation as of March 31, 2018:

Name of Subsidiary	Country of Incorporation
Taro Pharmaceuticals U.S.A., Inc.	United States
Taro Pharmaceuticals Inc.	Canada
Taro Pharmaceuticals North America, Inc.	Cayman Islands
Taro Pharmaceuticals Europe B.V.	Netherlands
Taro International Ltd.	Israel

The share capital of Taro U.S.A. is divided into two classes. The Company owns 96.9% of the shares that have economic rights and 50% of the shares that have voting rights in Taro U.S.A. 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. TDC has agreed to vote all of its shares in Taro U.S.A. for such persons as we may designate for any election to its board of directors; however, TDC may terminate the agreement upon one year's written notice.

The Company owns 100% of the shares of Taro International Ltd. and 100% of Taro Pharmaceuticals North America, Inc., which owns 100% of Taro Canada. The Company owns 99.75% of Taro Pharmaceuticals Europe B.V. and Taro Pharmaceuticals North America, Inc. owns the remaining 0.25%.

Sun beneficially owns 83.2% of the voting power of the Company as of March 31, 2018.

D. PROPERTY, PLANT AND EQUIPMENT

The following is a list of our principal facilities as of March 31, 2018:

Location	Square Footage	Main Use	Own/Lease
Haifa Bay, Israel	881,000	Pharmaceutical manufacturing, production and research laboratories, administration, and chemical production (including tank farm and chemical finishing plant)	Long-term Lease/ Own(1)

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Haifa Bay, Israel	31,000	Warehousing	Lease
Brampton, Canada	159,000	Pharmaceutical manufacturing, production and research laboratories, administration, distribution, and warehousing	Own
Brampton, Canada	89,000	Administration and warehousing	Lease
Hawthorne, New York	124,000	Administrative offices	Own
Cranbury, New Jersey	315,000	Distribution facility	Own

(1) The land housing the majority of our manufacturing, production laboratories and research facilities, as described above is held by the Company under a long-term lease from the Israeli Land Authority (“ILA”). The buildings and the vast majority of the equipment on this land are owned by the Company.

From April 1, 2015 through March 31, 2018, we invested \$81.6 million in property, plant and equipment. Most of these projects have been completed and are subject to depreciation in accordance with our accounting policy of capitalizing costs that are direct and incremental to the activities required to bring the facilities to commercial production. The Ireland facility was sold in July 2017.

Our manufacturing plant, research and office facilities in Haifa Bay, Israel are located in a complex of buildings with an aggregate area of 881,000 square feet. We lease much of the land underlying these facilities from the ILA pursuant to long-term ground leases that expire between 2018 and 2060. The Company has the right to extend the lease agreement ending 2018 for an additional period of 49 years and is in the process of extending the lease agreement. For additional information, please refer to Note 2.i. and 2.j. to our consolidated financial statements included elsewhere in this 2018 Annual Report.

We have owned our main manufacturing facility in Brampton, Canada since 1992. Since then, we have purchased additional adjacent square footage and engaged in projects to develop and expand the facility to meet our growing manufacturing needs. As of March 31, 2018, we owned a total of 159,000 square feet at our main manufacturing facility. In addition to our owned space, since September 2000, Taro Canada has leased 75,000 square feet of office and warehouse space, adjacent to our main manufacturing facilities, which lease term continues to September 2020. In December 2013, Taro Canada leased an additional 14,000 square feet of warehouse space near the two other facilities, which lease term continues to December 2021. The mortgage on this building was repaid in November 2010.

A subsidiary of Taro U.S.A. has owned its 124,000 square foot building in Hawthorne, New York since February 2005. The mortgage was repaid on this building in December 2015.

A subsidiary of Taro U.S.A. owns a 315,000 square foot distribution facility in Cranbury, New Jersey. The mortgage was repaid on this facility in February 2012.

In the pharmaceutical industry, both manufacturing plants and equipment must be constructed and installed in accordance with regulations designed to meet stringent quality and sterility guidelines, among others. In order to meet these requirements, certain validation processes are required to be completed prior to commencing commercial production.

Design qualification (“DQ”), installation qualification (“IQ”), operational qualification (“OQ”), performance qualification (“PQ”) and validation are the steps required by cGMPs to bring plants and/or equipment to the status of their intended use. In the performance of these activities, the Company uses both internal and external resources. The Company capitalizes external costs and those internal costs that are direct and incremental to the activities required to bring the facilities and activities to commercial production.

In the pharmaceutical industry, project life cycles (e.g., the construction of a new manufacturing facility) are typically longer than those in other industries. Such projects are technically complicated due to the highly regulated nature of the industry and the necessity of complying with specific detailed demands of regulatory authorities such as the FDA.

Certain internal resources utilized in bringing these facilities to the status required for their intended use are completely dedicated to these projects. The costs of personnel involved in such a process are capitalized only to the extent that they are directly dedicated to the completion of the facilities.

As described below, the nature of the activities performed by the employees whose salaries were capitalized include only the work and the direct costs associated with the factory acceptance test (“FAT”), the installation of equipment and the qualification and testing of the equipment prior to its commercial use.

The typical stages for defining the beginning and the completion of such construction projects include: planning and design of the facilities; construction; purchase, transportation and installation of equipment; equipment and facility validation (run in tests); and process and product validation.

All new equipment must undergo DQ, IQ, OQ and PQ in order to test and verify, according to written protocols, that all aspects of the equipment meet pre-determined specifications. IQ is defined as the documented evidence that the equipment has been installed according to the approved drawings and specifications. OQ is the documented evidence that all aspects of the equipment and the facility operate as intended within pre-determined ranges, according to the operational specifications. PQ is defined as the documented evidence that all aspects of the facility, utility or equipment that can affect product quality perform as intended in the pre-determined acceptance criteria.

Such qualification and validation activities are required for all equipment and systems that have an impact on or affect product quality and are required prior to commencing commercial production. At the time of installation and validation, all employees who will operate and maintain the equipment from the engineering, technology and maintenance departments are appropriately trained. At this stage in the installation and validation process, experts from the equipment manufacturer are on site, as part of the purchase contract, to provide training to Company employees in the operation and maintenance of the equipment.

This phase, which is necessary to bring the asset to the condition required for its intended use, is handled by a multi-functional team of engineers and technologists. The direct costs are the direct labor and the material consumed during this stage of installation and validation such as bottles, ampoules and raw materials. Incremental costs, which have arisen in direct response to the additional activity, include the expenses directly attributable to any employee's time fully dedicated to the project in question. After the equipment has passed all DQ, IQ, OQ and PQ tests, it is then tested for its ability to actually manufacture the specific products that are intended to be produced on the equipment. Three consecutive successful validation batches must be produced. This process is performed jointly by the technology and the manufacturing departments. In addition, the cleaning of the equipment must be validated to assure that there is no carry-over residue to the next product to be manufactured using the equipment. Only after the validation batches that are manufactured using the new equipment pass quality control and quality assurance tests can they be released for sale, completing the validation process. No further costs are capitalized. This process is performed for all products.

During the installation process, materials from inventory are consumed. For example, in order to qualify a tablet press machine or an ampoule filling machine, we use raw materials, including APIs and excipients, to run the qualification test. As part of this test, actual tablets are manufactured and costs are incurred. These tablets may neither be distributed nor sold. These qualification procedures are part of cGMPs mandated by the FDA and its international counterparts. The amount of inventory capitalized as part of these projects is less than one percent of the total cost of the assets. We do not capitalize, as part of the asset cost, inventories that are routinely produced in commercial quantities on a repetitive basis.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

A. OPERATING RESULTS

The following discussion should be read in conjunction with our consolidated financial statements and related notes for the years ended March 31, 2018, 2017 and 2016, which are included elsewhere in this 2018 Annual Report.

OVERVIEW

We are a multinational, science-based pharmaceutical company. We develop, manufacture and market Rx and OTC pharmaceutical products, primarily in the United States, Canada and Israel. We also develop and manufacture APIs primarily for use in our finished dosage form products. Our primary areas of focus include topical creams and ointments, liquids, capsules and tablets. We operate principally through three entities: Taro Israel and two of its subsidiaries, Taro Canada and Taro U.S.A.

The pharmaceutical industry is affected by demographic and socioeconomic trends, such as aging populations and increased demand for pharmaceuticals, as well as broad economic trends, resulting in a corresponding increase in

healthcare costs, effects on reimbursement pricing, and spending decisions of healthcare organizations, all of which lead to increased recognition of the importance of generics as providing access to affordable pharmaceuticals. We believe our business model is appropriately structured to take advantage of these trends.

The following is a breakdown of net sales by geographic region, including the percentage of our total consolidated net sales for each period:

	Year ended March 31,					
	2018		2017		2016	
Sales	% of total net sales	Sales	% of total net sales	Sales	% of total net sales	
	(in thousands)	(in thousands)	(in thousands)	(in thousands)	(in thousands)	(in thousands)
United States	\$549,174	83 %	\$785,319	89 %	\$865,224	91 %
Canada	67,226	10 %	57,621	7 %	56,605	6 %
Israel	38,223	6 %	29,200	3 %	22,963	2 %
Other	7,290	1 %	7,247	1 %	5,959	1 %
Total	\$661,913	100 %	\$879,387	100 %	\$950,751	100 %

We generate most of our revenue from the sale of Rx and OTC pharmaceutical products. Portions of our OTC products are sold as private label products primarily to chain drug stores, food stores, drug wholesalers, drug distributors and mass merchandisers in the United States. Three customers in the United States accounted for the following proportion of our total consolidated net sales:

Customer	Year ended March 31, 2018		2017		2016	
	% of total Sales		% of total Sales		% of total Sales	
	(in millions)	net sales	(in millions)	net sales	(in millions)	net sales
Customer A	\$ 101.2	15.3 %	\$ 125.0	14.2 %	\$ 134.0	14.1 %
Customer B	\$ 76.2	11.5 %	\$ 90.7	10.3 %	\$ 133.6	14.0 %
Customer C	\$ 75.1	11.4 %	\$ 169.3	19.3 %	\$ 190.4	20.0 %

Due to increased competition from other generic pharmaceutical manufacturers as they gain regulatory approvals to market generic products, selling prices and related profit margins tend to decrease as products mature. Thus, our future operating results are dependent on, among other factors, our ability to introduce new products. In addition, our operating results are dependent on the impact of pricing pressures on existing products. These pricing pressures are inherent in the generic pharmaceutical industry.

For the years ended March 31, 2018 and 2017, no product comprised 10% of our total consolidated sales. The percentage of net sales for products on a consolidated basis greater than 10% of our total consolidated sales in 2016 is:

Product	Year ended March 31,		
	2018	2017	2016
Clobetasol	*	*	10.7 %

*Less than 10%

Our sales are subject to market conditions and other factors. We are therefore unable to predict the extent, if any, to which the relative contribution to our total revenue of this product line as well as other product lines may increase or decrease in the future.

Cost of goods sold consists of direct costs and allocated costs. Direct costs consist of raw materials, packaging materials, royalties, and direct labor identified with a specific product. Allocated costs are costs not associated with a specific product.

Certain customary industry selling practices affect our level of working capital; for example, industry practice requires that pharmaceutical products be made available to customers on demand from existing stock levels rather than on a made-to-order basis. Therefore, in order to accommodate market demand, we try to maintain adequate levels of inventory. Increased demand for existing products and preparation for new product launches, the exact timing of which cannot be determined accurately, have generally resulted in higher levels of inventory. However, anticipated

growth in sales of any individual product, or of all products, may not materialize. Consequently, inventories prepared for these sales may become obsolete and have to be written off.

Another industry practice causes us to provide our customers with limited rights to return products, receive rebates, assert chargebacks and take other deductions with respect to sales that we make to them. See Item 5.A—"Operating Results—Critical Accounting Policies—Allowance for Sales Deductions and Product Returns." The exercise of these rights by customers to whom we have granted them has an impact, which may be substantial, upon our working capital.

We continuously monitor our aged receivables and our customers' creditworthiness. We also engage in active and intensive collection efforts as necessary.

CRITICAL ACCOUNTING POLICIES

Our significant accounting policies are described in Note 2 to our consolidated financial statements, which are prepared in conformity with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. We evaluate, on an ongoing basis, our estimates, including those related to bad debts, income taxes and contingencies. We base our estimates on currently available information, our historical experience and various other assumptions that we believe to be reasonable under the circumstances. The results of these assumptions are the basis for determining the carrying values of assets and liabilities that are not readily apparent from other sources. Since the factors underlying these assumptions are subject to change over time, the estimates on which they are based are subject to change accordingly.

The following is a summary of certain policies that have a critical impact upon our financial statements and, we believe, are most important to keep in mind in assessing our financial condition and operating results.

Use of Estimates. In preparing the consolidated financial statements, we use certain estimates and assumptions that affect reported amounts and disclosures. These estimates and underlying assumptions can impact all elements of our financial statements. We use estimates when accounting for product returns and sales deductions from revenues, determining the valuation and recoverability of assets (for example: accounts receivables, inventories, and intangible assets), and the reported amounts of accrued liabilities. We regularly evaluate our estimates and assumptions, using historical experience, third-party data, and market and external factors. Our estimates are often based on complex judgments, probabilities and assumptions that we believe to be reasonable but that are inherently uncertain and unpredictable. As future events and their effects cannot be determined with precision, our estimates and assumptions may prove to be incomplete or inaccurate, or unanticipated events and circumstances may occur that might cause us to change those estimates and assumptions. We adjust our estimates and assumptions when facts and circumstances indicate the need for change. It is possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range of alternative estimated amounts.

Revenue Recognition. We sell our products directly to wholesalers, retail drug store chains, mass merchandisers, grocery chains, other direct purchasers and customers that acquire our products indirectly through wholesalers.

We generally recognize revenue from product sales when title and risk of loss have transferred to our customers and when the criteria in the Financial Accounting Standards Board (the “FASB”) Accounting Standards Codification (“ASC”), Subtopic 605-15, “Revenue Recognition—Products” have been satisfied. Those criteria generally require that (i) persuasive evidence of an arrangement exists; (ii) product delivery has occurred; (iii) our price to our customers is fixed or determinable; (iv) collectability is reasonably assured; and (v) the amount of product returns, chargebacks, rebates and other sales deductions can be reasonably estimated. We ship products to our customers only in response to, and to the extent of, the orders that customers submit to us. Depending on the terms of our customer arrangements, revenue is generally recognized when the product is received by the customer (“FOB Destination Point”) or at the time of shipment (“FOB Shipping Point”).

Allowance for Sales Deductions and Product Returns. When we recognize and record revenue from the sale of our pharmaceutical products, we record an estimate in the same financial reporting period for product returns, chargebacks, rebates and other sales deductions, which are reflected as reductions of the related gross revenue. We regularly monitor customer inventory information at our three largest wholesale customers to assess whether any excess product inventory levels may exist. We review this information along with historical product and customer experience, third-party prescription data, industry and regulatory changes and other relevant information and revise our estimates as necessary.

Our estimates of inventory in the distribution channel are based on inventory information reported to us by our major wholesale customers, historical shipment and return information from our accounting records and third-party data on prescriptions filled. Our estimates are subject to inherent limitations pertaining to reliance on third-party information.

Product returns. Consistent with industry practice, we generally offer our customers the right to return inventory within three to six months prior to product expiration and up to 12 months thereafter (the “return period”). Product returns are identified by their manufacturing lot number. Because we manufacture in bulk, lot sizes are generally large and, therefore, shipments of a particular lot may occur over a one-to-three month period. As a result, although we cannot associate a product return with the actual shipment in which such lot was included, we can reasonably estimate the period (in months) over which the entire lot was shipped and sold. We use this information to estimate the average time period between lot shipment (and sale) and return for each product, which we refer to as the “return lag.” The shelf life of most of our products ranges between 18-36 months. Because returns of expired products are heavily concentrated during the return period, and given our historical data, we are able to reasonably estimate return lags for each of our products. These return lags are periodically reviewed and updated, as necessary, to reflect our

best knowledge of facts and circumstances. Using sales and return data (including return lags), we determine a rolling average monthly return rate to estimate our return reserves. We supplement this calculation with additional information including customer and product specific channel inventory levels, competitive developments, external market factors, our planned introductions of similar new products and other qualitative factors in evaluating the reasonableness of our return reserve. We continuously monitor factors that could affect our estimates and revise the reserves as necessary. Our estimates of expected future returns are subject to change based on unforeseen events and uncertainties.

We monitor the levels of inventory in our distribution channels to assess the adequacy of our product returns reserve and to identify potential excess inventory on hand that could have an impact on our revenue recognition. We do not ship product to our wholesalers when it appears that they have an excess of inventory on hand, based on demand and other relevant factors, for that particular product. Additionally, as a general practice, we do not ship products that have less than 12 months until expiration (i.e., “short-dated sales”).

Chargebacks. We have arrangements with certain customers that allow them to buy our products directly from wholesalers at specific prices. Typically these price arrangements are lower than the wholesalers' acquisition costs or invoice prices. In exchange for servicing these third party contracts, our wholesalers can submit a "chargeback" claim to us for the difference between the price sold to the third-party and the price at which it purchased the product from us. We generally pay chargebacks on generic products, whereas branded products are typically not eligible for chargeback claims. We consider many factors in establishing our chargeback reserves including inventory information from our largest wholesale customers and the completeness of their reports, estimates of Taro inventory held by smaller wholesalers and distributors, processing time lags, contract and non-contract sales trends, average historical contract pricing, actual price changes, actual chargeback claims received from the wholesalers, Taro sales to the wholesalers and other relevant factors. Our chargeback provision and related reserve varies with changes in product mix, changes in pricing, and changes in estimated wholesaler inventory. We review the methodology utilized in estimating the reserve for chargebacks in connection with analyzing our product return reserve each quarter and make revisions as considered necessary to reasonably estimate our potential future obligation.

Rebates and other deductions. We offer our customers various rebates and other deductions based primarily on their volume of purchases of our products. Chain wholesaler rebates are rebates that certain chain customers claim for the difference in price between what the chain customer paid a wholesaler for a product purchase and what the chain customer would have paid if such customer had purchased the same product directly from us. Cash discounts, which are offered to our customers, are generally 2% of the gross sales price, and provide our customers an incentive for paying within a specified time period after receipt of invoice. Medicaid rebates are earned by states based on the amount of our products dispensed under the Medicaid plan. Billbacks are special promotions or discounts provided over a specific time period to a defined customer base, and for a defined product group. Distribution allowances are a fixed percentage of gross purchases for inventory shipped to a national distribution facility that we pay to our top wholesalers on a monthly basis. Administration fees are paid to certain wholesalers, buying groups, and other customers for stocking our products and managing contracts and servicing other customers. Shelf stock adjustments, which are customary in the generic pharmaceutical industry, are based on customers' existing levels of inventory and the decrease in the market price of the related product. When market prices for our products decline, we may, depending on our contractual arrangements, elect to provide shelf-stock adjustments and thereby allow our customers with existing inventories to compete at the lower product price. We use these shelf-stock adjustments to support our market position and to promote customer loyalty.

The Company establishes reserves for rebates and these other various sales deductions based on contractual terms and customer purchasing activity, tracking and analysis of rebate programs, processing time lags, the level of inventory in the distribution channel and other relevant information. Based on our historical experience, substantially all claims for rebates and other sales deductions are received within 24 months.

Three-year summary

The following tables summarize the activities for sales deductions and product returns for the years ended March 31, 2018, 2017 and 2016:

For the year ended March 31, 2018 (in thousands)

Beginning	Provision	Credits	Ending
balance	recorded	processed/	balance
	for current	Payments	

period sales
(1)

Accounts Receivable Reserves

Chargebacks	\$(112,071)	\$(1,107,353)	\$1,102,792	\$(116,632)
Rebates and Other	(193,255)	(432,060)	492,094	(133,221)
Total	\$(305,326)	\$(1,539,413)	\$1,594,886	\$(249,853)

Current Liabilities

Returns	\$(82,494)	\$(49,265)	\$60,894	\$(70,865)
Other (2)	(43,370)	(60,677)	63,079	(40,968)
Total	\$(125,864)	\$(109,942)	\$123,973	\$(111,833)

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For the year ended March 31, 2017 (in thousands)

	Provision		Credits	
	recorded			
	Beginning	for current	processed/	Ending
	balance	period sales	Payments	balance
		(1)		
Accounts Receivable Reserves				
Chargebacks	\$(126,729)	\$(1,153,406)	\$1,168,064	\$(112,071)
Rebates and Other	(164,670)	(522,791)	494,206	(193,255)
Total	\$(291,399)	\$(1,676,197)	\$1,662,270	\$(305,326)
Current Liabilities				
Returns	\$(93,920)	\$(41,871)	\$53,297	\$(82,494)
Other (2)	(60,428)	(79,372)	96,430	(43,370)
Total	\$(154,348)	\$(121,243)	\$149,727	\$(125,864)

For the year ended March 31, 2016 (in thousands)

	Provision		Credits	
	recorded			
	Beginning	for current	processed/	Ending
	balance	period sales	Payments	balance
		(1)		
Accounts Receivable Reserves				
Chargebacks	\$(64,119)	\$(1,032,248)	\$969,638	\$(126,729)
Rebates and Other	(173,228)	(439,654)	448,212	(164,670)
Total	\$(237,347)	\$(1,471,902)	\$1,417,850	\$(291,399)
Current Liabilities				
Returns	\$(109,765)	\$(25,228)	\$41,073	\$(93,920)
Other (2)	(55,317)	(100,570)	95,459	(60,428)
Total	\$(165,082)	\$(125,798)	\$136,532	\$(154,348)

(1) Includes immaterial amounts of reversals of provisions recorded for prior years' sales.

(2) Includes indirect rebates and amounts due to customers.

Inventory. Inventories are stated at the lower of cost or market. Cost is determined as follows: raw and packaging materials mainly on a weighted-average cost basis; finished goods products and products still in process, mainly on a weighted-average production cost including direct and indirect, or overhead, manufacturing expenses. Our finished goods inventories generally have a limited shelf life and are subject to obsolescence as they approach their expiration dates. As a result, we record a reserve against our entire finished goods inventory with expiration dates of less than 12 months and use historical experience to estimate the reserve for products with expiration dates of more than 12 months from the balance sheet date. When available, we use actual data to validate our estimates. We regularly evaluate our policies and the carrying value of our inventories and establish a reserve against the carrying value of our

inventories. The determination that a valuation reserve is required, as well as the appropriate level of such reserve, requires us to utilize significant judgment. Although we make every effort to ensure the accuracy and reasonableness of our forecasts of future demand for our products, any significant unanticipated decreases in demand, or unanticipated changes in our major customer inventory management policies, could have a material impact on the carrying value of our inventories and reported operating results.

Valuation of Long-Lived Assets and Goodwill. We evaluate our long-lived assets for impairment and perform annual impairment testing for goodwill and other indefinite-lived intangible assets and other long-lived assets on March 31, when impairment indicators exist. Impairments are recorded for the excess of a long-lived assets' carrying value over fair value. Some examples of impairment indicators are as follows:

- ◆ Changes in legal or business climate that could affect an asset's value. For example, a failure to gain regulatory approval for a product or the extension of an existing patent that prevents our ability to produce a generic equivalent.
- ◆ Changes in our ability to continue using an asset. For example, restrictions imposed by the FDA could reduce our production and sales volume.
- ◆ Decreases in the pricing of our products. For example, consolidation among our wholesale and retail customers could place further downward pressure on the prices of some of our products.

We estimate the fair value of our long-lived assets other than goodwill, such as product rights, using a discounted cash flow analysis or market approach where appropriate when required under applicable U.S. GAAP. Under the discounted cash flow method, we estimate cash flows based on our forecasts and discount these cash flows using the appropriate rate to determine the net present value of the asset. The net present value of our assets is affected by several estimates, such as:

- The timing and amount of forecasted cash flows
- Discount rates
- Tax rates
- Regulatory actions
- Amount of competition
- Manufacturing efficiencies
- The number and size of our customers

For the years ended March 31, 2018, 2017 and 2016, the Company recorded \$0, \$0, and \$2 million impairment charges, respectively, primarily related to certain intellectual property as the Company is no longer selling a certain product.

We estimate the fair value of goodwill using a two-step procedure. First, we compare the market value of our equity to the carrying value of our equity. If the carrying value exceeds the market value of our equity, we calculate the implied fair value of our goodwill by taking the excess of our market capitalization over the fair value of our assets other than goodwill and obligations. An impairment is recorded for the difference between the implied fair value and carrying value of goodwill. The implied fair value of goodwill and any potential impairment is sensitive to estimates of the fair value of other assets and liabilities. We have not recorded any impairments of goodwill for the years ended March 31, 2018, 2017 and 2016.

Income Taxes. We determine deferred taxes by utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax basis of assets and liabilities under the applicable tax laws. Deferred taxes are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. On an annual basis, Management determines if it is more likely than not that we will not benefit from the deferred tax assets in certain subsidiaries. For any locations where this is determined, a full valuation allowance is provided against the deferred tax assets. In future years, if it is more likely than not that we will be in a position to utilize its deferred tax asset, the valuation allowance for such assets may be modified.

Discontinued Operations. Under ASC Subtopic 205-20, “Presentation of Financial Statements—Discontinued Operations,” when a component of an entity has been disposed of or classified as held for sale, the results of its operations, including the gain or loss on the disclosed component, should be classified as discontinued operations and the assets and liabilities of such component should be classified as assets and liabilities attributed to discontinued operations; that is, provided that the operations, assets and liabilities of the component have been eliminated from the entity’s consolidated operations and the entity will no longer have any significant continuing involvement in the operations of the component.

Recent Accounting Pronouncements that were recently adopted

In November 2015, The Financial Accounting Standards Board (the “FASB”) issued ASU No. 2015-17, “Income Taxes (Topic 740).” The amended guidance requires entities to present all deferred tax assets and liabilities, along with any related valuation allowance, as non-current on the balance sheet. The guidance was effective for the Company fiscal year that began April 1, 2017, including interim periods within that year. The amendments in this update could be applied either prospectively to all deferred tax liabilities and assets, or retrospectively to all periods presented. The Company applied the guidance prospectively and prior periods were not retrospectively adjusted.

Recent Accounting Pronouncements that may have an impact on future consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, “Intangibles—Goodwill and Other (Topic 350).” The new guidance reduces the complexity of goodwill impairment tests by no longer requiring entities to determine goodwill impairment by calculating the implied fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. The guidance will be effective for the Company fiscal year beginning April 1, 2020, including interim periods within that year on a prospective basis. The Company is currently evaluating the potential effect of the adoption of ASU 2017-04 on our financial position and results of operations.

In October 2016, the FASB issued ASU No. 2016-16, “Income Taxes (Topic 740).” The guidance requires that entities recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. The guidance will be effective for the Company fiscal year beginning April 1, 2018, including interim periods within that year. As a result of the intellectual property transfer from Taro North America (“TNA”) to Israel and Canada (as noted in “Item 8—Financial Information—Legal Proceedings”), the Company will recognize the income tax consequences of approximately \$41.4 million for deferred tax assets upon adoption of the guidance. The amendments in this update will be applied on a modified retrospective basis through a cumulative effect adjustment directly to retained earnings as of the beginning of the period of adoption.

In August 2016, the FASB issued ASU No. 2016-15, “Statement of Cash Flows (Topic 230).” The guidance addresses eight specific issues: debt prepayment or debt extinguishment costs, settlement of certain debt instruments, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees, beneficial interest in securitization transactions, separately identifiable cash flows and application of predominance principle. The guidance will be effective for the Company fiscal year beginning April 1, 2018, including interim periods within that year. The adoption of ASU 2016-15 is not expected to have a material impact on our Statement of Cash Flows.

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments—Credit Losses (Topic 326).” The guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance will be effective for the Company fiscal year beginning April 1, 2020, including interim periods within that year. The Company is currently evaluating the potential effect of the adoption of ASU 2016-13 on our financial position and results of operations.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842).” The new guidance requires that the lessee recognize the assets and liabilities that arise from leases. The guidance will be effective for the Company fiscal year beginning April 1, 2019, and interim periods within that year. The Company is currently evaluating the potential effect of the adoption of ASU 2016-02 on our financial position and results of operations.

In January 2016, the FASB issued ASU No. 2016-01, “Financial Instruments-Overall (Subtopic 825-10).” The amended guidance focuses on the recognition and measurement of financial assets and liabilities. The guidance will be effective for the Company fiscal year beginning April 1, 2018, including interim periods within that year. The adoption of ASU 2016-01 is not expected to have a material impact on our financial position and results of operations.

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers (Topic 606), Section A—Summary and Amendments that Create Revenue from Contracts with Customers (Topic 606) and Other Assets and Deferred Costs—Contracts with Customers (Subtopic 340-40).” The amended guidance will enhance the comparability of revenue recognition practices and will be applied to all contracts with customers. Improved disclosures related to the nature, amount, timing, and uncertainty of revenue that is recognized are requirements under the amended guidance. The guidance is effective for the interim and annual periods beginning on or after December 15, 2017 (early adoption is permitted for the interim and annual periods beginning on or after December 15, 2016), as a result of the FASB announcing a one year deferral. Either a full retrospective method or modified retrospective method is permitted. The Company will adopt the guidance for the fiscal year beginning April 1, 2018, including interim periods within that year, and expects to use the modified retrospective method. The Company does not currently anticipate the adoption to have a material impact on our financial position or results of operations.

RESULTS OF OPERATIONS

The following table sets forth selected items from our consolidated statements of operations as a percentage of total sales:

Consolidated Statements of Operations	For the year ended March 31,		
	2018	2017	2016
Sales, net	100.0%	100.0%	100.0%
Cost of sales	30.0 %	23.7 %	17.9 %
Impairment	0.0 % *		0.2 %
Gross profit	70.0 %	76.3 %	81.9 %
Operating expenses:			
Research and development	10.6 %	8.0 %	7.5 %
Selling, marketing, general and administrative	13.3 %	9.7 %	9.7 %
Settlements and loss contingencies	0.3 % *		0.1 %
Total operating expenses	24.2 %	17.7 %	17.3 %
Operating income	45.8 %	58.6 %	64.6 %
Financial expenses (income), net	1.9 %	(3.9 %)	(2.1 %)
Other gain, net	0.3 %	1.3 %	0.3 %
Income before income taxes	44.2 %	63.8 %	67.0 %
Tax expense	12.4 %	11.8 %	10.0 %
Income from continuing operations	31.8 %	52.0 %	57.0 %
Net loss from discontinued operations attributable to Taro	*	*	*
Net income	31.8 %	52.0 %	57.0 %
Net (loss) income attributable to non-controlling interest	(0.2 %) *		*
Net income attributable to Taro	32.0 %	52.0 %	57.0 %

*Less than 0.05%

YEAR ENDED MARCH 31, 2018 COMPARED WITH YEAR ENDED MARCH 31, 2017

Sales. For the year ended March 31, 2018, sales decreased \$217.5 million, or 24.7%, compared to the same period in 2017. Sales in the United States during the year ended March 31, 2018 decreased \$236.1 million or 30.1%, compared to the same period in 2017. We continue to experience a difficult generic pricing environment, particularly in the U.S., driven by more intense competition among manufacturers, new entrants to the market, buying consortium pressures, and a higher ANDA approval rate from the FDA. There are no products in the year ended March 31, 2018 or 2017 that represent more than 10.0% of consolidated net sales. The Company actively manages its product portfolio to assess pricing relative to market dynamics. Sales in Israel and other international markets increased \$9.1 million, or 24.9%, primarily due to new launches and increased market share on certain products. Sales in Canada increased \$9.6 million, or 16.7%, compared to the year ended March 31, 2017, due to new launches and increased market share on certain products. Total Company volumes increased 5.8% as compared to 2017.

Cost of Sales. Cost of sales, as a percentage of net sales, increased to 30.0% in the year ended March 31, 2018, compared to 23.7% in 2017. This increase is primarily related to increased sales volumes compared to prior year, product mix, and the challenging pricing environment effecting net selling price.

Gross Profit. The Company's gross profit was \$463.5 million, or 70.0% of net sales, in the year ended March 31, 2018, while gross profit was \$671.3 million, or 76.3% of net sales in the same period in 2017. The decrease in 2018 was primarily the result of increased competition and the challenging pricing environment, as noted above.

Research and Development. Research and development ("R&D") expenses decreased \$0.2 million in the year ended March 31, 2018, compared to the previous year. The decrease in R&D expenses was primarily the result of lower clinical study expenses. As a percentage of net sales R&D expenses increased 2.6% to 10.6% in the year ended March 31, 2018, compared to the previous year.

Selling, Marketing, General and Administrative. In the year ended March 31, 2018, selling, marketing, general and administrative ("SMG&A") expenses increased \$2.5 million. As a percentage of net sales, SMG&A increased to 13.3% from 9.7%.

Settlements and Loss Contingencies. Settlements and loss contingencies expense was \$1.9 million in the year ended March 31, 2018, compared to an expense of \$0 million in 2017 primarily due to a withholding tax settlement in Israel.

Operating Income. In the year ended March 31, 2018, the Company had operating income of \$303.0 million compared to \$515.0 million in the same period in 2017, a decrease of \$211.9 million. Operating income, as a percentage of sales, decreased to 45.8% in the year ended March 31, 2018 from 58.6% in the same period in 2017.

Financial Expenses (Income), Net. Financial income, net results principally from interest income and the impact of foreign currency exchange rate fluctuations. Net financial expense was \$12.5 million in the year ended March 31, 2018, compared to an income of \$34.6 million for the year ended March 31, 2017. The change in financial expense (income), net is the result of FX expense of \$32.5 million for 2018 compared to FX income of \$20.2 million in 2017 an unfavorable impact of \$52.6 million, principally the result of the strength of the CAD versus the U.S. dollar; slightly offset by an increase in interest and other financial income of \$5.5 million to \$19.9 million.

Taxes. Tax expense in the year ended March 31, 2018 was \$82.0 million, compared to \$103.8 million in the same period in 2017, a decrease of \$21.8 million. The effective tax rate increased to 28.0% from 18.5%. During the third quarter of year ended March 31, 2018, the Company recorded a \$38.0 million expense for the impact of the re-measurement of the Company's estimated net deferred tax asset, as a result of the Tax Cuts and Job Act. Excluding the impact from the one-time re-measurement, tax expense would have been \$44.0 million with an effective tax rate of 15.0%. The Company recognized \$29.5 million of tax loss carry-forwards and investment tax credits.

Net Income attributable to Taro. Net income decreased \$245.2 million to \$211.2 million for the year ended March 31, 2018, from \$456.4 million in the prior year, by reason of the factors noted above.

YEAR ENDED MARCH 31, 2017 COMPARED WITH YEAR ENDED MARCH 31, 2016

Sales. For the year ended March 31, 2017, sales decreased \$71.4 million, or 7.5%, compared to the same period in 2016. Sales in the United States during the year ended March 31, 2017 decreased \$79.9 million or 9.2%, compared to the same period in 2016. We continue to experience a difficult generic pricing environment, particularly in the U.S., driven by more intense competition among manufacturers, new entrants to the market, buying consortium pressures, and a higher ANDA approval rate from the FDA. There are no products in the year ended March 31, 2017, that represent more than 10.0% of consolidated net sales; while Clobetasol represented 10.7% in 2016. The Company actively manages its product portfolio to assess pricing relative to market dynamics. Sales in Israel and other international markets increased \$7.5 million, or 26.0%, primarily due to increased volumes on certain products. Sales in Canada increased \$1.0 million, or 1.8%, compared to the year ended March 31, 2016, due to increased market share on certain products. Total Company volumes increased 2% as compared to 2016 on the strength of our generic business.

Cost of Sales. Cost of sales, as a percentage of net sales, increased to 23.7% in the year ended March 31, 2017, compared to 17.9% in 2016. This increase is primarily related to increased sales volumes of 2% compared to prior year, in addition to the challenging pricing environment effecting net selling price, product mix and increased royalties.

Gross Profit. The Company's gross profit was \$671.3 million, or 76.3% of net sales, in the year ended March 31, 2017, while gross profit was \$779.0 million, or 81.9% of net sales in the same period in 2016. The decrease in 2017 was primarily the result of increased competition and the challenging pricing environment, as noted above.

Research and Development. Research and development ("R&D") expenses decreased \$0.5 million in the year ended March 31, 2017, compared to the previous year. The decrease in R&D expenses was primarily the result of lower clinical study expenses. As a percentage of net sales R&D expenses increased 0.5% to 8.0% in the year ended March 31, 2017, compared to the previous year.

Selling, Marketing, General and Administrative. In the year ended March 31, 2017, selling, marketing, general and administrative ("SMG&A") expenses decreased \$6.7 million primarily as a result of reduced Kevevis® spend and

certain other savings. As a percentage of net sales, SMG&A remained flat at 9.7%.

Settlements and Loss Contingencies. Settlements and loss contingencies expense was \$0 million in the year ended March 31, 2017, compared to an expense of \$1.0 million in 2016 primarily due to the Utah AWP settlement.

Operating Income. In the year ended March 31, 2017, the Company had operating income of \$515.0 million compared to \$614.5 million in the same period in 2016, a decrease of \$99.5 million. This decrease is primarily attributed to the decrease in gross profit, which is partially offset by lower SMG&A expenses. Operating income, as a percentage of sales, decreased to 58.6% in the year ended March 31, 2017 from 64.6% in the same period in 2016.

Financial Income, Net. Financial income, net results principally from interest income and the impact of foreign currency exchange rate fluctuations. Net financial income was \$34.6 million in the year ended March 31, 2017, compared to \$19.7 million for the year ended March 31, 2016, an increase of \$15.0 million, or 76.1%. The change in financial income, net from 2016 to 2017 reflects the favorable impact of the change in foreign currency exchange rates related primarily to the cash and cash equivalents, short-term bank deposits and intercompany balances in Canada. This is principally driven by the strengthening of the U.S. dollar compared to the CAD at a slightly lower rate compared to the prior year.

Taxes. Tax expense in the year ended March 31, 2017 was \$103.8 million, compared to \$95.3 million in the same period in 2016, an increase of \$8.5 million. The effective tax rate increased 3.5% mainly due to the recognition of \$36.0 million of tax loss carry-forwards and investment tax credits resulting from the acquisition of Zalicus in 2016. As of March 31, 2017, we had carryforward tax losses of \$11.1 million in the United Kingdom, \$18.6 million in Canada, and \$67.2 million in Ireland.

Net Income attributable to Taro. Net income decreased \$84.6 million to \$456.4 million for the year ended March 31, 2017, from \$540.9 million in the prior year, by reason of the factors noted above.

IMPACT OF INFLATION, DEVALUATION (APPRECIATION) AND EXCHANGE RATES ON RESULTS OF OPERATIONS, LIABILITIES AND ASSETS

We conduct manufacturing, marketing and research and development operations primarily in Israel, Canada and the United States. As a result, we are subject to risks associated with fluctuations in the rates of inflation and foreign exchange in each of these countries.

The following table sets forth the annual rate of (deflation) inflation, the (appreciation) devaluation rate of the NIS and the CAD against the U.S. dollar and the exchange rates between the U.S. dollar and each of the NIS and the CAD at the end of the period indicated:

	Rate of (Deflation)		Rate of (Appreciation)		Rate of Exchange of	
	Inflation		Devaluation		U.S. Dollar	
	Israel	Canada	Against U.S. Dollar		Israel	Canada
Period ended	(1)	(2)	Israel (1)	Canada (2)	(1)	(2)
3/31/2016	(0.71 %)	1.27 %	(5.28			