PERRIGO CO
Form 10-K
August 16, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended June 30, 2012
or
[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number 0-19725
Perrigo Company
(Exact name of registrant as specified in its charter)

Michigan	38-2799573
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
515 Eastern Avenue Allegan, Michigan	49010
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (269) 673-8451
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock (without par value)	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act:
None
(Title of Class)
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES [X] NO [ ]
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 of Section 15(d) of the Act. YES [ ] NO [X]
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 [X] 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 [X] NO [ ]
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting

company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [X]	Accelerated filer [ ]
Non-accelerated filer [ ]	Smaller reporting company [ ]

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). [ ] YES [X] NO

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on December 30, 2011 as reported on The NASDAQ Global Select Market, was $8,435,657,798. Shares of common stock held by each director or executive officer have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of August 10, 2012, the registrant had 93,504,825 outstanding shares of common stock.

Documents incorporated by reference:

Portions of the Registrant's Proxy Statement for its Annual Meeting of Shareholders on November 6, 2012 are incorporated by reference into Part III of this Form 10-K.

PERRIGO COMPANY
FORM 10–K
FISCAL YEAR ENDED JUNE 30, 2012
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this report are “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created thereby. These statements relate to future events or the Company’s future financial performance and involve known and unknown risks, uncertainties and other factors that may cause the actual results, levels of activity, performance or achievements of the Company or its industry to be materially different from those expressed or implied by any forward-looking statements. In particular, statements about the Company’s expectations, beliefs, plans, objectives, assumptions, future events or future performance contained in this report, including certain statements contained in “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” are forward-looking statements. In some cases, forward-looking statements can be identified by terminology such as “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “potential” or the negative of thos other comparable terminology. The Company has based these forward-looking statements on its current expectations, assumptions, estimates and projections. While the Company believes these expectations, assumptions, estimates and projections are reasonable, such forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond the Company’s control. These and other important factors, including those discussed under “Risk Factors,” may cause actual results, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. The forward-looking statements in this report are made only as of the date hereof, and unless otherwise required by applicable securities laws, the Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I.

Item 1. Business. (Dollar amounts in thousands)

GENERAL

Perrigo Company, established in 1887, is a leading global healthcare supplier that develops, manufactures and distributes over-the-counter ("OTC") and generic prescription ("Rx") pharmaceuticals, infant formulas, nutritional products and active pharmaceutical ingredients ("API"). The Company is the world’s largest store brand manufacturer of OTC pharmaceutical products and infant formulas. The Company’s primary markets and locations of manufacturing and logistics operations are the United States ("U.S."), Israel, Mexico, the United Kingdom ("U.K.") and Australia. Perrigo Company operates through several wholly owned subsidiaries. In the U.S., its operations are conducted primarily through L. Perrigo Company, Perrigo Company of South Carolina, Inc., Perrigo New York, Inc., Perrigo Holland, Inc., PBM Holdings, Inc., Paddock Laboratories, LLC and Perrigo Diabetes Care, LLC (formerly CanAm Care, LLC). Outside the U.S., its operations are conducted primarily through Perrigo Israel Pharmaceuticals Ltd., Chemagis Ltd., Quimica y Farmacia S.A. de C.V., Laboratorios Diba, S.A., Wrafton Laboratories Limited, Galpharm Healthcare Ltd. and Orion Laboratories Pty Ltd. As used herein, references to the “Company” mean Perrigo Company, its subsidiaries and all predecessors of Perrigo Company and its subsidiaries.

The Company’s principal executive offices are located at 515 Eastern Avenue, Allegan, Michigan, 49010. Its telephone number is (269) 673-8451. The Company’s website address is http://www.perrigo.com, where the Company makes available free of charge the Company’s reports on Forms 10-K, 10-Q and 8-K, as well as any amendments to these reports, as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission ("SEC"). These filings are also available to the public at http://www.sec.gov and http://www.isa.gov.il.

The Company has four reportable segments, aligned primarily by type of product: Consumer Healthcare, Nutritionals, Rx Pharmaceuticals and API. In addition, the Company has an Other category that consists of the Israel Pharmaceutical and Diagnostic Products operating segment, which does not individually meet the quantitative thresholds required to be a separately reportable segment. In the fourth quarter of fiscal 2010, the Company acquired PBM Holdings, Inc. ("PBM"), the leading manufacturer and distributor of store brand infant formulas, pediatric nutritionals and baby foods. As a result of the acquisition of PBM, the Company began participating in new nutritional

product lines. In the first quarter of fiscal 2011, the Company realigned and expanded its operating segments to include a Nutritionals segment, representing infant formulas and other nutritional products. Management makes operating decisions, allocates resources and manages the growth and profitability of

the Company’s business according to these operating segments. As a result of the change in segment reporting, all historical segment information has been adjusted to conform to the new presentation.

Prior to June 27, 2010, the Company’s consolidated results of operations and financial position included the financial results of its U.K., Mexico, Germany and Israel subsidiaries on a twelve-month period ending in May, resulting in a one-month reporting lag when compared to the remainder of the Company. Starting June 27, 2010, the reporting year-end of these foreign operations was changed from May to June. The previously existing one-month reporting lag was eliminated as it was no longer required to achieve a timely consolidation due to the Company’s investments in technology, ERP systems and personnel to enhance its financial statement close process. The Company believes this change is preferable because financial information of all operating units is now reported based on the same period-end, which improves overall financial reporting to investors by providing the most current information available. The Company’s financial statements for periods prior to fiscal 2011 have been adjusted to reflect the period-specific effects of applying this change in accounting principle.

In March 2009, the Company committed to a plan to sell its Israel Consumer Products business. This business primarily sold consumer products to the Israeli market, including cosmetics, toiletries and detergents, and was previously reported as part of the Company’s Other category. The sale was completed in the third quarter of fiscal 2010. In the fourth quarter of fiscal 2012, upon satisfaction of contingency factors specified in the sale agreement, the Company received additional consideration of $8,639, which was included in discontinued operations. The final pre-tax gain on the sale of the Israel Consumer Products business was $7,238. See Note 3 of the Notes to Consolidated Financial Statements for additional information concerning the sale of Israel Consumer Products. The results of the Israel Consumer Products business prior to the sale were reported as a discontinued operation, and as a result, all consolidated financial statements in this Annual Report on Form 10-K for periods prior to the sale have been adjusted accordingly to reflect this financial statement presentation.

Information concerning sales and operating income attributable to each of the Company’s business segments and geographic areas for the last three fiscal years ended on or around June 30 is set forth in Item 7 Management’s Discussion and Analysis of Financial Condition and Results of Operations and in Note 17 of the Notes to Consolidated Financial Statements. Information concerning identifiable assets of each of the Company’s reportable segments as of the last three fiscal years ended on or around June 30 is set forth in Note 17 of the Notes to Consolidated Financial Statements.

CONSUMER HEALTHCARE

The Consumer Healthcare segment is the world’s largest store brand manufacturer of OTC pharmaceutical products. This reportable segment markets a broad line of products that are comparable in quality and effectiveness to national brand products. Major product categories include analgesics, cough/cold/allergy/sinus, gastrointestinal and smoking cessation, and secondary product categories include feminine hygiene, diabetes care and dermatological care. The cost to the retailer of a store brand product is significantly lower than that of a comparable nationally advertised brand-name product. The retailer, therefore, can price a store brand product below the competing national brand product yet realize a greater profit margin on the store brand item. Generally, the retailers’ dollar profit per unit of store brand product sold is greater than the dollar profit per unit of the comparable national brand product. The consumer benefits by receiving a high quality product at a price below the comparable national brand product. Therefore, the Company's business model saves consumers on their annual healthcare spending. The Company, one of the original architects of private label pharmaceuticals, is the market leader for consumer healthcare products in many of the geographies where it currently competes – the U.S., U.K., and Mexico – and is developing a leadership position in Australia. The Company's market share of store brand private label OTC products has grown in recent years as new products, retailer efforts to increase consumer education and awareness and economic events have directed consumers to the value of store brand product offerings.

Significant Developments

On January 6, 2012, the Company acquired substantially all of the assets of CanAm Care, LLC ("CanAm"), a distributor of diabetes care products, located in Alpharetta, Georgia, for $39,014. The purchase price included an up-front cash payment of $36,114 and contingent consideration totaling $2,900 based primarily on the estimated fair

value of contingent payments to the seller pending the Company's future execution of a promotion agreement with a third-party related to a certain diabetes care product. See Note 5 of the Notes to Consolidated Financial Statements regarding the valuation of the $2,900 contingent consideration. The acquisition expanded the Company's diabetic product offering within the Consumer Healthcare segment. CanAm's results of operations were recorded in the Consumer Healthcare segment beginning in the Company's third quarter of fiscal 2012.

Consumer Healthcare Business

The Company is dedicated to being the leader in developing and marketing new store brand products and has a research and development staff that management believes is one of the most experienced in the industry at developing products comparable in formulation and quality to national brand products. This staff also responds to changes in existing national brand products by reformulating existing Company products. In the OTC pharmaceutical market, certain new products are the result of changes in product status from “prescription only” (Rx) to OTC (non-prescription). These “Rx-to-OTC switches” require approval by the FDA, a process initiated by the drug innovator, through either the FDA Abbreviated New Drug Application ("ANDA") or its New Drug Application ("NDA"). As part of its strategy, the Company relies on both internal development and strategic product development agreements with outside sources. In addition, the Company also engages in contract manufacturing which focuses on partnerships with major pharmaceutical, multi-level marketing and direct-to-consumer companies by providing unique ANDA and monograph products to its contract customers to maximize sales of proprietary formulas and to utilize available capacity.

The Company is committed to consistently providing its customers with high quality products that adhere to “Current Good Manufacturing Practices” ("cGMP") regulations promulgated by the FDA and the health ministries of countries where the Company has commercial and operational presence. Substantially all products are developed using ingredients and formulas comparable to those of national brand products. In most instances, packaging is designed to increase visibility of store brand products and to invite and reinforce comparison to national brand products in order to communicate store brand value to the consumer.

The Company seeks to establish customer loyalty through superior customer service by providing a comprehensive assortment of high quality, value priced products; timely processing, shipment and delivery of orders; assistance in managing customer inventories and support in managing and building the customer’s store brand business. The Company also seeks to establish customer loyalty by providing marketing support that is directed at developing customized marketing programs for the customers’ store brand products. The primary objective of this store brand management approach is to enable customers to increase sales of their own store brand products by communicating store brand quality and value to the consumer. The Company’s sales and marketing personnel assist customers in the development and introduction of new store brand products and the promotion of customers’ ongoing store brand products by performing consumer research, providing market information and establishing individualized promotions and marketing programs.

The Consumer Healthcare segment currently markets over 2,100 store brand products, with over 9,000 stock-keeping units ("SKUs"), to over 800 customers. The Company considers every different combination of size, flavor, strength and dosage form (e.g., tablet, liquid, softgel, etc.) of a given item as a separate “product”. The Company also currently manufactures and markets certain products under its Good Sense® brand.

Listed below are major Consumer Healthcare product categories under which the Company markets products for store brand labels; the annual retail market size for retailers in the U.S. (according to SymphonyIRI Group); and the names of certain national brands against which the Company’s products compete.

Product Categories	Retail Market Size (Billions)	Comparable National Brands
Cough/Cold/Allergy/Sinus	$6.0	Afrin®, Allegra®, Benadryl®, Claritin®, Dimetapp®, Mucinex®, NyQuil®, DayQuil®, Robitussin®, Sudafed®, Tavist®, Theraflu®, Triaminic®, Tylenol®, Zaditor®, Zyrtec®
Gastrointestinal	$4.0	Imodium A-D®, Maalox®, MiraLAX®, Mylanta®, Pepcid® AC, Pepto Bismol®, Phillips®, Prevacid®, Prilosec OTC®, Tagamet HB®, Tums®, Zantac®
Analgesics	$3.5	Advil®, Aleve®, Bayer®, Excedrin®, Motrin®, Tylenol®
Smoking Cessation	$0.8	Nicorette®

The Company’s U.S.-based customers are major national and regional retail drug, supermarket and mass merchandise chains, including Walmart, CVS, Walgreens, Kroger, Target, Dollar General, Rite Aid, Sam’s Club and Costco, and major wholesalers, including McKesson, Cardinal Health and AmerisourceBergen.

The Consumer Healthcare segment employs its own sales force to service larger customers and uses industry brokers for some retailers. Field sales employees, with support from marketing and customer service, are assigned to specific customers in order to understand and work most effectively with the customer. They assist customers in developing in-store marketing programs for consumers and optimize communication of customers' needs to the rest of the Company. Industry brokers provide a distribution channel for some products, primarily those marketed under the Good Sense® label.

In contrast to national brand manufacturers, which incur considerable advertising and marketing expenditures targeted directly to the end consumer, the Consumer Healthcare segment's primary marketing efforts are channeled through its customers, the retailers and wholesalers, and reach the consumer through its customers' in-store marketing programs. These programs are intended to communicate store brand value to the consumer by increasing visibility of store brand products and inviting comparison to national brand products. Merchandising vehicles such as floor displays, bonus sizes, coupons, rebates, store signs and promotional packs are incorporated into customers' programs. Because the retailer profit margin for store brand products is generally higher than for national brand products, retailers and wholesalers often commit funds for additional promotions. The Company's marketing efforts are also directed at new product introductions and product conversions, as well as providing market data. Market analysis and research is used to monitor trends for individual products and product categories and develop category management recommendations.

New Product Introductions and Drug Application Approvals

The Company launched various new products in fiscal 2012, most notably lansoprazole 15 mg capsules, loratadine-D 12 hour extended release tablets and minoxidil 5% foam, which compete with the national brands Prevacid® 15 mg capsules, Claritin-D®12 hour extended release tablets and Rogaine® 5% foam, respectively. Net sales related to all new products were $101,700 for fiscal 2012, $54,200 for fiscal 2011 and $65,700 for fiscal 2010. A Consumer Healthcare product is considered new if it was added to the Company's product lines within 12 months prior to the end of the period for which net sales are being measured.

In fiscal 2012, the Company, on its own or in conjunction with partners, received approval from the FDA for five OTC drug applications. The applications were for the following products:

- dextromethorphan polistirex suspension
- guaifenesin extended release 600 mg tablets
- lansoprazole 15 mg capsules
- nicotine coated cinnamon 2 mg gum
- nicotine coated cinnamon 4 mg gum

As of June 30, 2012, the Company, on its own or in conjunction with partners, had 11 OTC drug applications pending approval with the FDA.

Collaboration Agreements

The Company actively partners with other pharmaceutical companies to collaboratively develop, manufacture and market certain products or groups of products. These types of agreements are not uncommon in the pharmaceutical industry. The Company may choose to enter into these types of agreements to, among other things, leverage its or others' scientific research and development expertise or utilize its extensive marketing and distribution resources. See Note 1 of the Notes to Consolidated Financial Statements for more information regarding the Company's method for recognizing revenue and expenses related to collaboration agreements, as well as Note 19 of the Notes to Consolidated Financial Statements for more information regarding the Company's current collaboration agreements.

Competition

The market for OTC pharmaceutical products is highly competitive. Competition is based on a variety of factors, including price, quality and assortment of products, customer service, marketing support and availability of and approvals for new products. The Company believes it competes favorably in these areas.

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The Company’s competition in store brand products consists of several publicly traded and privately owned companies, including brand-name pharmaceutical companies. The competition is highly fragmented in terms of both geographic market coverage and product categories, such that a competitor generally does not compete across all product lines. Some of the Company’s competitors are Dr. Reddy’s Laboratories, Ltd., Watson Pharmaceuticals, Actavis Group hf., Aaron Industries, Inc., Ohm Laboratories, Inc., PL Developments and LNK International, Inc. The Company’s store brand products also compete with nationally advertised brand-name products. Most of the national brand companies have financial resources substantially greater than those of the Company. National brand companies could in the future manufacture more store brand products or lower prices of their national brand products. Additionally, the competitive landscape has changed to where generic prescription drug manufacturers have elected to pursue OTC marketing status for products that have switched or are switching from Rx to OTC status.

NUTRITIONALS

The Nutritionals segment develops, manufactures, markets and distributes store brand infant and toddler formula products, infant and toddler foods, vitamin, mineral and dietary supplement ("VMS") products, and oral electrolyte solution ("OES") products to retailers, distributors and consumers primarily in the U.S., Canada, Mexico and China. Similar to the Consumer Healthcare segment, this business markets store brand products that are comparable in quality and formulation to the national brand products. The cost to the retailer of a store brand product is significantly lower than that of a comparable nationally advertised brand-name product. The retailer, therefore, can price a store brand product below the competing national brand product yet realize a greater profit margin. All infant formulas sold in the U.S. are subject to the same regulations governing manufacturing and ingredients under the Infant Formula Act of 1980, as amended ("Formula Act"). Store brands, which are value priced and offer substantial savings to consumers, must meet the same FDA nutritional requirements as the national brands. Substantially all products are developed using ingredients and formulas comparable to those of national brand products. In most instances, packaging is designed to increase visibility of store brand products and to invite and reinforce comparison to national brand products in order to communicate store brand value to the consumer.

Significant Developments

In the third quarter of fiscal 2012, the Company made the decision to restructure its workforce and cease all remaining manufacturing production at its Florida facility by the end of fiscal 2012. This facility manufactured the Company's OES products that are part of the Nutritionals reporting segment. In connection with the restructuring, the Company transitioned production to a more efficient, service-oriented supply chain, and incurred restructuring charges of $7,081 and $1,674 in the third and fourth quarters of fiscal 2012, respectively. The Company does not expect to incur any additional charges related to this restructuring plan. See Note 18 of the Notes to Consolidated Financial Statements for additional information regarding the Company's Florida restructuring plan.

Nutritionals Business

The Company is dedicated to being the leader in developing and marketing new store brand products and has a research and development staff that management believes is one of the most experienced in the industry at developing products comparable in formulation and quality to national brand products. This staff also responds to changes in national brand products by reformulating existing Company products. As part of its strategy, the Company relies on both internal development and strategic product development agreements with outside sources.

The Company seeks to establish customer loyalty through superior customer service by providing a comprehensive assortment of high quality, value priced products; timely processing, shipment and delivery of orders; assistance in managing customer inventories and support in managing and building the customer’s store brand business. The Company also seeks to establish customer loyalty by providing marketing support that is directed at developing customized marketing programs for the customers’ store brand products. The primary objective of this store brand management approach is to enable customers to increase sales of their own store brand products by communicating store brand quality and value to the consumer. The Company’s sales and marketing personnel assist customers in the development and introduction of new store brand products and the promotion of customers’ ongoing store brand products by performing consumer research, providing market information and establishing individualized promotions

and marketing programs.

The Nutritionals segment currently markets over 400 store brand products, with over 2,400 SKUs, to over 200 customers. The Company considers every different combination of size, flavor, formulation (e.g., milk-based, soy-based, etc.), strength and form (e.g., tablet, liquid, softgel, etc.) of a given item as a separate "product".
Listed below are major Nutritional product categories under which the Company markets products for store brand labels; the annual retail market size for retailers in the U.S. (according to SymphonyIRI Group); and the names of certain national brands against which the Company's products compete.

Product Categories	Retail Market Size (Billions)		Comparable National Brands
Dietary Supplements	$5.8		Centrum®, Flintstones®, One-A-Day®, Caltrate®, Osteo Bi-Flex®
Infant Formulas	$3.9	(1)	Similac®, Enfamil®, Gerber Good Start®, Earth's Best®
Baby & Toddler Foods	$1.5		Gerber®, Beechnut®, Pedialyte®

(1) Includes Special Supplemental Nutrition Program for Women, Infants and Children ("WIC") market.
The Company's U.S.-based customers are major national and regional retail drug, supermarket and mass merchandise chains, including Walmart, CVS, Walgreens, Kroger, Target, Sam's Club and Costco, as well as major wholesalers, including McKesson.
The Nutritionals segment employs its own sales force to service larger customers and uses industry brokers for some retailers. Field sales employees, with support from marketing and customer service, are assigned to specific customers in order to understand and work most effectively with the customer. They assist customers in developing in-store marketing programs for consumers and optimize communication of customers' needs to the rest of the Company.

The Nutritionals segment's primary marketing efforts are channeled through its customers, the retailers and wholesalers, and reach the consumer through its customers' in-store marketing programs and other customer- specific vehicles. These programs are intended to increase visibility of store brand products and to invite comparisons to national brand products in order to communicate store brand value to the consumer. Merchandising vehicles such as floor displays, bonus sizes, coupons, rebates, store signs and promotional packs are incorporated into customers' programs. Other traditional consumer marketing vehicles such as print advertising, direct mail and on-line communications are also employed to a limited extent. Because the retailer profit margin for store brand products is generally higher than for national brand products, retailers and wholesalers often commit funds for additional promotions. In addition to in-store marketing programs, the Nutritionals segment markets directly to consumers and healthcare professionals in an effort to drive initiation.
New Product Introductions
Net sales related to new products were $69,800 for fiscal 2012, $16,500 for fiscal 2011 and $4,500 for fiscal 2010. Fiscal 2012 new product sales primarily relate to the transition to next generation formulas within the product portfolio. A Nutritionals product is considered to be new if it was added to the Company's product lines within 12 months prior to the end of the period for which net sales are being measured.
Competition
The market for infant formula and nutritional products is highly competitive. Competition is based on a variety of factors, including price, quality and assortment of products, customer service, marketing support and availability of and approvals for new products. The Company believes it competes favorably in these areas.
The Company's competition in store brand products consists of several publicly traded and privately owned companies, including brand-name pharmaceutical companies. Some of the Company's competitors for infant formula are Abbott Laboratories, Mead Johnson Nutrition Co. and Nestle S.A. (Gerber). Most of the national brand companies have financial resources substantially greater than those of the Company. National brand companies could in the future manufacture more store brand products or lower prices of their national brand products. The Company competes in the VMS area with a number of publicly traded and privately owned companies, some of which have broader product lines and larger nutrition category sales volumes than those of the Company.

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PRESCRIPTION PHARMACEUTICALS

The Rx Pharmaceuticals segment develops, manufactures and markets a portfolio of generic prescription drugs for the U.S. market. The Company defines this portfolio as predominantly “extended topical” and specialty as it encompasses a broad array of topical dosage forms such as creams, ointments, lotions, gels, shampoos, foams, suppositories, sprays, liquids, suspensions, solutions and powders. The portfolio also includes select controlled substances, injectables, hormones, oral liquids and oral solid dosage forms.

Significant Developments

On July 26, 2011, the Company completed the acquisition of substantially all of the assets of Paddock Laboratories, Inc. ("Paddock"). After final working capital and other adjustments, the ultimate cash paid for Paddock was $546,215. Headquartered in Minneapolis, Minnesota, Paddock was a manufacturer and marketer of generic Rx pharmaceutical products. As part of closing the acquisition, the Company divested a small portfolio of generic pharmaceutical products in response to the Federal Trade Commission ("FTC") review of the transaction. The acquisition expanded the Company's generic Rx product offering, pipeline and scale. Paddock's results of operations were recorded in the Company's Rx Pharmaceuticals segment beginning in the Company's first quarter of fiscal 2012.

On September 21, 2009, the Company acquired the ANDA for clindamycin phosphate (1%) and benzoyl peroxide (5%) gel from KV Pharmaceutical for $14,000 in cash and a $2,000 milestone payment to be made upon the successful completion of a contingency. This product is the generic equivalent of Duac® gel, which is marketed by Stiefel Laboratories, and is indicated for the topical treatment of inflammatory acne vulgaris. Excluding the milestone payment, the full amount of the purchase price, which related to acquired research and development, was capitalized and immediately written off as in-process research and development in the first quarter of fiscal 2010 because the ANDA had not received final FDA approval at the date of acquisition. In the fourth quarter of fiscal 2012, upon successful completion of the contingency, the Company paid KV Pharmaceutical the $2,000 milestone payment, which was charged to earnings in the fourth quarter of fiscal 2012. On June 27, 2012, the Company launched this product upon receiving final FDA approval for its ANDA.

Rx Business

The Company develops, manufactures and markets primarily generic "extended topical" and other specialty prescription pharmaceuticals. Topical and specialty products are manufactured at the Company’s New York, Minnesota and Israel facilities and are also sourced from various FDA-approved third parties. The Company also manufactures certain other generic products, namely oral solids and oral liquids at its Michigan facilities. The Company’s current development areas include other delivery systems such as nasal sprays, oral liquids, injectables (with third parties) and transdermal products. Other areas of expertise include the production capabilities for controlled substance and hormonal products. Pharmaceuticals are manufactured, labeled and packaged in facilities that comply with strict regulatory standards and meet customers’ stringent requirements.

In addition, the Rx Pharmaceuticals segment offers OTC products through the prescription channel (referred to as “ORx®” marketing). ORx® products are OTC products that are available for pharmacy fulfillment and healthcare reimbursement when prescribed by a physician. The Company offers over 100 ORx® products that are reimbursable through many health plans, Medicaid and Medicare programs. When prescribed by a doctor or other health care professional, ORx® products offer consumers safe and effective remedies that provide an affordable alternative to higher out-of-pocket costs of traditional OTC products. The Company’s ORx® strategy is to register OTC products for reimbursement through public and private health plans, as well as leverage its portfolio and pipeline of OTC products for generic substitution when appropriate.

The Rx Pharmaceuticals segment currently markets approximately 400 generic prescription products, with almost 1,000 SKUs, to approximately 300 customers. A SKU for a generic prescription product is a unique combination of the product’s package size, ingredient strength and dosage form (e.g., tablet, syrup, cream, foam, ointment, gel, etc.). The Company generally holds the ANDA or product application for the drugs that it manufactures or enters into an arrangement with the application holder for the manufacture and/or marketing of certain products.

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Listed below are the major generic prescription products, including ORx® products, that the Company manufactures and/or distributes:

Generic Name	Competitive Brand-Name Drug
Adapalene cream	Differin®
Ammonium lactate cream and lotion	Lac-Hydrin®
Benzoyl peroxide gel	Benzac®
Cetirizine tablets and syrup	Zyrtec®
Ciclopirox shampoo	Loprox®
Clindamycin phosphate and benzoyl peroxide gel	Duac®
Clindamycin phosphate foam and solution	Evoclin®, CleocinT®
Clindamycin palmitate hydrochloride	Cleocin®
Clobetasol foam and lotion	Olux®, Clobex®
Econazole nitrate cream	Spectazole®
Erythromycin and benzoyl peroxide gel	Benzamycin®
Erythromycin pads	Erycette®, T-Stat®
Fluticasone ointment and cream	Cutivate®
Griseofulvin oral suspension	Grifulvin V®
Halobetasol ointment and cream	Ultravate®
Hydroquinone cream	Epiquin®
Ibuprofen oral suspension	Motrin®
Imiquimod cream	Aldara®
Ketoconazole shampoo	Nizoral®
Levocetirizine tablets	Xyzal®
Liothyronine sodium tablets	Cytomel®
Mesalamine rectal suspension enema	Rowasa®
Mometasone cream, ointment and lotion	Elocon®
Mupirocin ointment	Bactroban®
Nytatin topical powder	Mycostatin®
Omeprazole tablets	Prilosec®
Permethrin cream	Elimite®
Polyethylene glycol 3350	MiraLAX®
Salicylic acid shampoo	Salex®
Selenium sulfide shampoo	Selsun®
Sodium sulfacetamide wash	Ovace ®
Terconazole suppositories	Terazol 3®
Testosterone cypionate injection	Depo®
Tretinoin cream and gel	Retin-A®
Triamcinolone acetonide nasal spray	Nasacort® AQ

The Company’s U.S.-based customers are major wholesalers, including Cardinal Health, McKesson and AmerisourceBergen, as well as national and regional retail drug, supermarket and mass merchandise chains, including Walgreens, Walmart, CVS, Rite Aid, Kroger and Safeway. Generic prescription drugs are sold to the consumer through the pharmacy counter of predominantly the same retail outlets as OTC pharmaceuticals and nutritional products.

New Product Introductions and Drug Application Approvals

The Company recently launched several new generic or authorized generic prescription products, including ketoconazole foam, levocetirizine syrup, clobetasol lotion, epinistine HCl ophthalmic solution and clindamycin phosphate and benzoyl peroxide gel, which contain the same active ingredients present in the same dosage forms as

Extina®, Xyzal®, Clobex®, Elestat® and Duac®, respectively. Net sales related to new products were approximately $35,100 for fiscal 2012, which includes $6,400 launched by the newly acquired Paddock business, $81,100 for fiscal 2011 and $34,600 for fiscal 2010. An Rx Pharmaceuticals product is considered new if it was added to the Company's product lines within 12 months prior to the end of the period for which net sales are being measured.

In fiscal 2012, the Company, on its own or in conjunction with partners, received final approval from the FDA for eight generic prescription drug applications. The applications were for the following products:

- acarbose tablets
- butoconazole nitrate vaginal cream
- calcium acetate tablets
- clindamycin phosphate and benzoyl peroxide gel
- desloratadine 5 mg tablets
- epinistine ophthalmic solution
- ketoconazole foam
- levocetirizine syrup

As of June 30, 2012, the Company, on its own or in conjunction with partners, had 37 generic Rx drug applications pending approval with the FDA.

Collaboration Agreements

The Company actively partners with other pharmaceutical companies to collaboratively develop, manufacture and market certain products or groups of products. These types of agreements are not uncommon in the pharmaceutical industry. The Company may choose to enter into these types of agreements to, among other things, leverage its or others' scientific research and development expertise or utilize its extensive marketing and distribution resources. See Note 1 of the Notes to Consolidated Financial Statements for more information regarding the Company's method for recognizing revenue and expenses related to collaboration agreements, as well as Note 19 of the Notes to Consolidated Financial Statements for more information regarding the Company's current collaboration agreements.

Competition

The market for generic prescription drugs is subject to intense competition from other generic drug manufacturers, brand-name pharmaceutical companies launching their own generic version of a branded product (known as an authorized generic), manufacturers of branded drug products that continue to produce those products after patent expirations and manufacturers of therapeutically similar drugs. Among the Company's competitors in the topical generics market are Glenmark Generics Inc., Sandoz, Taro Pharmaceutical, Teva Pharmaceutical Industries Ltd., Tolmar, Triax Pharmaceuticals, Watson Pharmaceuticals and Zydus Pharmaceuticals, as well as brand-name pharmaceutical companies where the Company offers a generic equivalent.

The Company believes that one of its primary competitive advantages is its ability to introduce difficult to develop and/or manufacture topical and other specialty generic equivalents to brand-name drug products. Generally, these products are exposed to less competition due to the relatively longer development, clinical trial and approval processes. In addition, the Company believes it has a favorable competitive position due primarily to its efficient distribution systems, topical production economies of scale, customer service and overall reputation.

Price competition from additional generic versions of the same product, as well as potential price competition from the original branded or authorized generic products, may result in a significant and/or rapid decline in sales and profit margins. In addition, competitors may also develop their products more rapidly or complete the regulatory approval process sooner and market their products earlier than the Company. New drugs and future developments in improved and/or advanced drug delivery technologies or other therapeutic techniques may provide therapeutic or cost advantages to competing products.

Many brand-name competitors try to prevent, discourage or delay the use of generic equivalents through various measures, including introduction of new branded products, legislative initiatives, changing dosage forms or dosing regimens just prior to introduction of a generic equivalent, regulatory processes, filing new patents or patent extensions, lawsuits, citizens' petitions and negative publicity. In addition, brand-name companies sometimes launch, either through an affiliate or licensing arrangements with another company, an authorized generic at or near the time the first generic product is launched, depriving the generic product market exclusivity intended by the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act ("Hatch-Waxman"). For more information See Information

Applicable to All Reported Segments – Government Regulation – U.S. Food and Drug Administration.

Many of the Company’s customers, which include chain drug stores, wholesalers, distributors, hospital systems and group purchasing organizations, continue to merge or consolidate. In addition, a number of its customers have instituted source programs limiting the number of suppliers of generic pharmaceutical products carried by that customer. As a result of these developments, heightened competition exists among generic drug producers for business from this smaller and more selective customer base.

ACTIVE PHARMACEUTICAL INGREDIENTS

The Company develops, manufactures and markets API used worldwide by the generic drug industry and branded pharmaceutical companies. Certain of these ingredients are used in its own pharmaceutical products. The manufacturing of these API occurs primarily in Israel. This segment is undergoing a strategic platform transformation, moving certain production from Israel to the acquired API manufacturing facility in India to allow for lower cost production and to create space for other, more complex production in Israel.

Significant Developments

The Company has had a long-standing commercial agreement with a customer to supply an API for use in a generic finished dosage pharmaceutical product that was launched in the fourth quarter of fiscal 2012. Due to unexpected developments in that market formation, the Company's customer was able to launch its product with 180-day exclusivity status. As a result, the Company's API operating results were positively impacted by approximately $11,000. While the Company expects to continue to recognize favorable contributions related to this agreement, it also expects the magnitude of the contribution to significantly decrease after the 180-day exclusivity period, which will end during the Company's second quarter of fiscal 2013.

Over the past several years, the Company has been developing the API temozolomide for various finished dose partners in several global markets. In the third quarter of fiscal 2010, the Company launched temozolomide into the European market. On February 2, 2010, the Company announced that it will exclusively supply Teva Pharmaceutical Industries Ltd. ("Teva") with the API for the generic version of Temodar® (temozolomide) in the U.S. market. Teva will manufacture, market and distribute the product in the U.S., and the Company will share equally with Teva in the profitability of the product sold. Teva was the first company to file an ANDA that contained a Paragraph IV certification for Temodar®. On January 26, 2010, the United States District Court for the District of Delaware held that the patent protecting temozolomide was unenforceable. On March 1, 2010, the FDA granted final approval to the Teva ANDA, but Teva did not launch the product at that time. Merck appealed the ruling and on November 9, 2010, the appeals court reversed the trial decision, preventing the launch of the Teva product. Teva filed a petition for the entire appeals court to rehear the case, and on February 29, 2011 the court denied the motion. In response, Teva filed a petition for certiorari with the United States Supreme Court that was denied, ending the litigation. By agreement between Teva and Merck, Teva will not be able to launch the product until August 2013.
In the fourth quarter of fiscal 2009, the Company evaluated the API business in the context of the expected future competitive dynamics in API and the Company’s strategic focus on specialty molecules and vertical integration. Management determined that its German API facility was no longer competitive from a global cost position. At that time, the Company did not anticipate that there would be a viable market for the sale of this facility and related operations, and accordingly, the Company planned to cease all operations at the facility during the first quarter of fiscal 2011. During the third quarter of fiscal 2010, however, the Company was approached by an external party who offered to buy the German API facility and related operations from the Company. Subsequent to the third quarter of fiscal 2010, the Company signed an agreement and closed the transaction with the third-party buyer for the sale of the German API facility and related operations. As part of its German restructuring plan, the Company incurred net charges of $6,775 and $2,049 in the third and fourth quarters of fiscal 2010, respectively. See Note 18 of the Notes to Consolidated Financial Statements for additional information regarding the sale of the German API facility and related operations.

To further improve the long-term cost position of its API business, on August 6, 2009, the Company acquired an 85% stake in Vedants Drug & Fine Chemicals Private Limited ("Vedants"), an API manufacturing facility in India, for $11,500 in cash. The facility, located approximately 30 miles outside of Mumbai, is currently under construction and will manufacture the Company’s current and future high-volume API products, as well as expand the Company’s vertical integration of Rx and future candidate Rx-to-OTC switch products. Manufacturing of API at this facility is expected to begin at the end of fiscal 2013, with shipments expected to commence in fiscal 2014, and will include certain API products currently manufactured in Israel and those that had been manufactured in

Germany.
The Company actively enters into exclusive marketing and sales agreements (dossier agreements) related to specific product formulations, for specific geographic areas, for specific periods of time. The Company recognized revenue related to certain dossier agreements of approximately $200, $500 and $9,100 in fiscal 2012, 2011 and 2010, respectively. The Company intends to continue pursuing similar types of agreements in the future.

API Business
The API business identifies APIs that will be critical to its pharmaceutical customers' future product launches and then works closely with these customers on the development processes.
API development is focused on the synthesis of less common molecules for the U.S., European and other international markets. The Company is also focusing development activities on the synthesis of molecules for use in its own OTC and Rx pipeline products. This vertical integration may enable the Company to be more competitive on pricing of its other product lines and to broaden its growth and profit opportunities. The Company believes it has a competitive advantage in its ability to produce difficult-to-develop products through its understanding of regulatory issues, patents, and chemistry. Because of the difficulty in developing these products and the related regulatory challenges, the lead time to market a product can be long. The Company's ability to continue to develop and market new products that have lower levels of competition is key to driving profitability in the API business.
The API business sells to customers who face similar regulatory oversight as the Company's Rx Pharmaceuticals business. As a result, the API business is dependent on these customers' ability to obtain proper product approvals and maintain regulatory compliance with the FDA, the FTC, and the U.S. Drug Enforcement Administration ("DEA"), as well as several foreign, state and local agencies in localities in which the Company's products are sold.
Because the Company's API customers depend on high quality supply and regulatory support, the Company focuses on rigorous quality assurance, quality control and regulatory compliance as part of its strategic positioning. The Company's quality system is designed to comply with the regulatory requirements of the FDA, the European Medicines Agency and the Australian Therapeutic Goods Administration. The Company is regularly inspected by various regulatory authorities and customers.
The Company places a high priority on responding to client needs and requirements from project initiation through final production. It offers support throughout the development stage, preparation of Drug Master Files ("DMF") and assistance throughout the approval process. The API segment is supported by sales offices in the U.S. and Israel and sales agents in various other countries.
The Company currently manufactures and markets to generic and branded pharmaceutical companies worldwide the following API products:

Ammonium lactate
Anastrozole
Azacitidine
Cetirizine dihydrochloride
Cilostazol
Cisatracurium
Donepezil hydrochloride
Exemestane
Fenofibrate
Flumazenil
Fluticasone propionate
Gemcitabine
Granisetron hydrochloride
Halobetasol
Imiquimod
Lamotrigine
Levocetirizine dihydrochloride
Midazolam base
Midazolam hydrochloride
Midazolam maleate
Modafinil
Mometasone furoate
Montelukast sodium
Moxonidine
Pentoxifylline
Pramipexole dihydrochloride
R-Modafinil
Rocuronium bromide
Temozolomide
Terbinafine hydrochloride
Tramadol hydrochloride
Zonisamide

Letrozole

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New Product Introductions

Net sales related to new products were approximately $7,100 for fiscal 2012, $32,000 for fiscal 2011, and $15,300 for fiscal 2010. Fiscal 2011 new product sales primarily relate to sales to the European market of temozolomide, which the Company launched during the third quarter of fiscal 2010. An API product is considered new if it was added to the Company's product lines or sold to a new geographic area with different regulatory authorities within 12 months prior to the end of the period for which net sales are being measured.

Competition

The API segment operates in a highly competitive, price sensitive market in which the Company's customers continue to consolidate and/or vertically integrate, thereby creating a smaller customer base. Since other manufacturers of API typically do not offer all of the same product lines or serve all of the same markets as the Company's API segment, the segment competes on a product-by-product basis with a number of different competitors. The Company's API business is subject to increased price competition from other manufacturers of API located mostly in India, China and Europe. This competition may result in the loss of API clients and/or decreased profitability in this business segment. However, the Company believes that its regulatory position, market reputation, client relationships and ability to manufacture difficult-to-develop API provide it with a favorable competitive position.

OTHER

The Company has an Other category comprised of Israel Pharmaceutical and Diagnostic Products, which does not meet the quantitative threshold required to be a separately reportable segment. Israel Pharmaceutical and Diagnostic Products includes the marketing and manufacturing of branded prescription drugs under long-term exclusive licenses and the importation of pharmaceutical, diagnostics and other medical products into Israel based on exclusive agreements with the manufacturers.

Discontinued Operations

In March 2009, the Company committed to a plan to sell its Israel Consumer Products business. Israel Consumer Products consisted of cosmetics, toiletries, bar soaps and detergents generally sold under the Company's brand names Careline®, Neca® and Natural Formula®. The financial results of this business, which were previously reported as part of the Company's Other category, have been classified as discontinued operations in the consolidated financial statements for all periods presented. The assets and liabilities of this business are reflected as assets and liabilities of discontinued operations in the consolidated balance sheets for all periods presented. On February 26, 2010, the Company completed the sale of its Israel Consumer Products business to Emilia Group, a subsidiary of O. Feller Holdings Ltd., for approximately $47,000, of which approximately $11,000 was contingent upon satisfaction of contingency factors specified in the agreement. In the fourth quarter of fiscal 2012, upon satisfaction of these contingency factors, the Company received additional consideration of $8,639, which was included in discontinued operations. As a result, the final pre-tax gain on the sale of the Israel Consumer Products business was $7,238. See Note 3 of the Notes to Consolidated Financial Statements for additional information regarding discontinued operations.

Competition

The Company's Other category operates in competitive markets. These markets are based primarily in Israel, but the Company is also subject to competition in those markets from large multi-national companies looking to expand their position in the local Israeli market. In most instances, these companies are significantly larger than the Company on a global basis with greater financial resources and product lines. The Company also has several significant product supply agreements with outside vendors. As a result, the Company's competitive position is largely dependent on its ability to maintain these agreements. The Company believes that its competitive advantages consist of its historical knowledge of the local markets and strong local brand recognition.

INFORMATION APPLICABLE TO ALL REPORTABLE SEGMENTS

Research and Development

Research and development are key components of the Company's business strategy and, while managed centrally on a global basis, are performed in various locations in the U.S. and abroad. Development for both the Consumer

Healthcare and Nutritionals markets focuses on products comparable or better in formulation, quality and

effectiveness to existing national brand OTC products, nutritional supplement products, infant formulas and Rx-to-OTC switch products. Development of generic prescription drugs, primarily for the U.S. market, focuses on complex formulations, many of which require costly clinical endpoint trials. Development of API for the global market also focuses on complex products with high barriers to entry. While the Company conducts a significant amount of its own research and development, it also enters into strategic alliance agreements to obtain the rights to manufacture and/or distribute new products.

Research and development spending was $105,774 for fiscal 2012, $89,250 for fiscal 2011 and $83,515 for fiscal 2010. Fiscal 2012 included incremental research and development expenses attributable to the Paddock acquisition. Fiscal 2010 included charges of $14,000 and $5,000 for the write-offs of in-process research and development related to the ANDAs acquired from KV Pharmaceuticals and Novel, respectively. The Company anticipates that research and development expenditures will increase above fiscal 2012 levels in dollar terms but remain relatively flat as a percentage of sales in the foreseeable future as the Company continues to cultivate its presence in the generic pharmaceutical market and to develop its internal research and development capabilities.

Trademarks and Patents

The Company owns certain trademarks and patents; however, its business as a whole is not materially dependent upon its ownership of any one trademark or patent or group of trademarks or patents.

Significant Customers

The Company believes its primary customer base aligns with the concentration of large drug retailers in the current marketplace of the retail drug industry. Walmart accounted for 20% of consolidated net sales for fiscal 2012, 22% for fiscal 2011 and 23% for fiscal 2010. Should Walmart's current relationship with the Company change adversely, the resulting loss of business would have a material adverse impact on the Company's consolidated operating results and financial position. The Company does not anticipate such a change in the foreseeable future. In addition, while no other customer individually comprises more than 10% of total net sales, the Company does have other significant customers. The Company currently has generally good relationships with all of its customers. If the Company's relationship with one or more of these other customers, including the terms for doing business with the customers, changes significantly, it could have a material adverse impact on the Company's financial position and results of operations.

Manufacturing and Distribution

The Company's primary manufacturing facilities are located in the U.S. and Israel (see Item 1A. Risk Factors – Conditions in Israel for further information). The Company also has secondary manufacturing facilities located in the U.K., Mexico and Australia, along with joint ventures located in China and India. The Company supplements its production capabilities with the purchase of product from outside sources. During fiscal 2012, the approximate average capacity utilization was 70% and 90% for the Company's facilities in the U.S. and Israel, respectively. The capacity of some facilities may be fully utilized at certain times due to various reasons, such as customer demand, the seasonality of the cough/cold/flu season and new product launches. The Company may utilize available capacity by contract manufacturing for other companies.

The Company has logistics facilities located in the U.S., Israel, the U.K., Mexico and Australia. Both contract freight and common carriers are used to deliver products.

Seasonality

Revenues in the Company's Consumer Healthcare segment are generally subject to the seasonal demands for cough/cold/flu and allergy products in its second and third fiscal quarters. Historically, the Company's sales of these products have varied from year to year based in large part on the severity and length of the cough/cold/flu season. While the Company believes that the severity and length of the cough/cold/flu season will continue to impact its sales of cough/cold/flu and allergy products, there can be no assurance that the Company's future sales of these products will necessarily follow historical patterns. Revenues for the Nutritionals, Rx Pharmaceuticals and API segments, as well as the Other category, are generally not impacted significantly by seasonal conditions.

Materials Sourcing

Affordable high quality raw materials and packaging components are essential to all of the Company's business units due to the nature of the products it manufactures. Raw materials and packaging components are generally available

from multiple suppliers. While the Company has the ability to manufacture and supply certain

API materials for the Consumer Healthcare segment, certain components and finished goods are purchased rather than manufactured because of temporary production limitations, FDA restrictions or economic and other factors. Supplies of certain raw materials, bulk tablets and components are limited, or are available from one or only a few suppliers. Historically, the Company has been able to react to situations that require alternate sourcing. Should alternate sourcing be required, FDA requirements placed on products approved through the ANDA or NDA process could substantially lengthen the approval of an alternate source and adversely affect financial results. The Company has good, cooperative working relationships with substantially all of its suppliers and has historically been able to capitalize on economies of scale in the purchase of materials and supplies due to its volume of purchases.

Environmental

The Company is subject to various environmental laws and regulations. The Company believes that the costs for complying with such laws and regulations will not be material to the business of the Company. The Company does not have any material remediation liabilities outstanding.

In March and June of 2007, lawsuits were filed by three separate groups against both the State of Israel and the Council of Ramat Hovav in connection with waste disposal and pollution from several companies, including the Company, that have operations in the Ramat Hovav region of Israel. These lawsuits were subsequently consolidated into a single proceeding in the District Court of Beer-Sheva. The Council of Ramat Hovav, in June 2008, and the State of Israel, in November 2008, asserted third-party claims against several companies, including the Company. The pleadings allege a variety of personal injuries arising out of the alleged environmental pollution. Neither the plaintiffs nor the third-party claimants were required to specify a maximum amount of damages, but the pleadings allege damages in excess of $72,500, subject to foreign currency fluctuations between the Israeli shekel and the U.S. dollar. While the Company intends to vigorously defend against these claims, the Company cannot reasonably predict at this time the outcome or the liability, if any, associated with these claims.

Corporate Social Responsibility

The Company has a strong commitment to doing business in an ethical manner. The Company has a long history of environmentally sound and efficient operations, safe and healthy working conditions, and active participation in the communities where the Company is located.

The Company's Corporate Social Responsibility Commitment Statement highlights seven areas at the heart of its efforts:

- Helping consumers access safe, effective and affordable healthcare products
- Complying with regulatory and legal requirements
- Demonstrating environmental stewardship
- Continuously improving packaging sustainability
- Protecting human rights of its global employees and challenging its partners to do the same
- Providing a safe and healthy work environment for its employees
- Establishing effective community partnerships

Through these efforts, the Company can minimize its impact on the environment, drive responsible business practices and ensure the welfare of its employees now and into the future.

Government Regulation

The manufacturing, processing, formulation, packaging, labeling, testing, storing, distributing, advertising and sale of the Company’s products are subject to regulation by one or more U.S. agencies, including the FDA, the FTC, the DEA, the USDA and the Consumer Product Safety Commission ("CPSC"), as well as several foreign, state and local

agencies in localities in which the Company's products are sold. In addition, the Company manufactures and markets certain of its products in accordance with standards set by organizations, such as the United States Pharmacopeial Convention, Inc. ("USP") and NSF International ("NSF"). The Company believes that its policies, operations and products comply in all material respects with existing regulations.

U.S. Food and Drug Administration
The FDA has jurisdiction over the Company's ANDA, NDA and OTC monograph drug products, dietary

supplements, infant formulas and medical food products. The FDA's jurisdiction extends to the manufacturing, testing, labeling, packaging, storage and distribution of these products.

OTC and Generic Prescription Pharmaceuticals. Many of the Company's OTC pharmaceutical products are regulated under the OTC monograph system and subject to certain FDA regulations. OTC monographs have been established through the FDA's OTC Review utilizing the notice-and-comment rulemaking procedures. Under the OTC monograph system, selected OTC drugs are generally recognized as safe and effective and do not require the submission and approval of an ANDA or NDA prior to marketing. The FDA OTC monographs include well-known ingredients and specify requirements for permitted indications, required warnings and precautions, allowable combinations of ingredients and dosage levels. Drug products marketed under the OTC monograph system must conform to specific quality, formula and labeling requirements; however, these products generally can be developed and marketed with fewer regulatory hurdles than those products that require the filing of an ANDA or NDA. It is, in general, less costly to develop and bring to market a product produced under the OTC monograph system. From time to time, adequate information may become available to the FDA regarding certain ANDA or NDA drug products that will allow the reclassification of those products as no longer requiring the approval of an ANDA or NDA prior to marketing. For this reason, there may be increased competition and lower profitability related to a particular product should it be reclassified to the OTC monograph system. The FDA and USP have embarked on an initiative to modernize the monograph requirements of OTC drugs. The Company is monitoring the situation and will make appropriate adjustments to remain in compliance. In addition, regulations may change from time to time, requiring formulation, packaging or labeling changes for certain products. The Company cannot predict whether new legislation regulating the Company's activities will be enacted or what effect any legislation would have on the Company's business.

The Company also markets generic prescription drugs and other products that have switched from prescription to OTC status through an application process initiated by the innovator company that holds the original clinical trial data. These products require approval by the FDA through its ANDA or NDA processes prior to commercialization. Based on current FDA regulations, ANDAs and NDAs provide information on chemistry, manufacturing and change control, bioequivalence, packaging and labeling. The development process for a generic drug generally requires less time and expense than the development process for a new drug. For approval of an ANDA, the Company must demonstrate that the product is bioequivalent to a marketed product that has previously been approved by the FDA and that the Company's manufacturing process meets FDA standards. The approval process for an ANDA may require that bioequivalence studies be performed using a small number of subjects in a controlled clinical environment, and for certain topical generic products, demonstration of efficacy in comparative full end-point clinical studies. Depending on the specific product, other types of studies may be required by the FDA. The median approval time for the industry currently averages over 32 months from the date an ANDA is submitted, an increase from 31 months a year ago. Changes to a product marketed under an ANDA or NDA are governed by specific FDA regulations and guidelines that define when proposed changes can be implemented and whether prior FDA notice and/or approval is required.

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act), a company submitting an NDA can obtain a three-year period of marketing exclusivity for an Rx product or an Rx to OTC switch product if the company performs a clinical study that is essential to FDA approval of the NDA. Longer periods of exclusivity are possible for new chemical entities and orphan drugs. These exclusivity periods prevent other companies from obtaining approval of any ANDAs for a similar or equivalent generic product. Where three years of exclusivity is granted to the initiating company, the Company will be unable to market the product unless the Company establishes a relationship with the company having exclusive marketing rights. There can be no assurance that, in the event the Company applies for FDA approvals, the Company will obtain the approvals to market Rx, Rx to OTC switch products or OTC ANDA products or, alternatively, that the Company will be able to obtain these products from other manufacturers.

Under the Federal Food, Drug and Cosmetic Act ("FFDCA"), a manufacturer may obtain an additional six months (which, under certain circumstances, may be extended to one year) of exclusivity if the innovator conducts pediatric studies requested by the FDA on the product. This exclusivity will, in certain instances, delay FDA approval and the sales by the Company of certain ANDA and other products.

If the Company is first to file its ANDA and meets certain requirements relating to the patents owned or licensed by the brand company, the Company may be entitled to a 180-day generic exclusivity period for that product. When a company submits an ANDA, the company is required to include a patent certification to certain patents that are identified with the innovator product. If the ANDA applicant challenges the validity of the innovator's patent or certifies that its product does not infringe the patent, the product innovator may sue for infringement. The

legal action would not ordinarily result in material damages but could prevent the Company from introducing the product if it is not successful in the legal action. The Company would, however, incur the cost of defending the legal action and that action could have the effect of triggering a statutorily mandated delay in FDA approval of the ANDA for a period of up to 30 months from when the innovator was notified of the patent challenge. In addition, if exclusivity is granted to the Company, there can be no assurance that the Company will be able to market the product at the beginning of the exclusivity period or that the exclusivity will not be shared with other generic companies, including authorized generics. It is possible that more than one applicant files the first ANDA on the same day and exclusivity is shared. This may happen by chance, but more likely when there is a certain type of innovator exclusivity that prevents the filing of all ANDAs until a specific date. As a result of events that are outside of the Company's control, the Company may forfeit its exclusivity. Finally, if the Company is not first to file its ANDA, the FDA may grant 180-day exclusivity to another company, thereby effectively delaying the launch of the Company's product.

The Company's prescription drug products that are marketed without approved applications must meet certain manufacturing and labeling standards established by the FDA. The FDA's policy with respect to the continued marketing of unapproved products is stated in the FDA's September 2011 compliance policy guide, titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those marketed as unapproved drugs with potential safety risks or that lack evidence of effectiveness. The FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, among other things, have been marketed for many years and, at this time, might not be subject to immediate enforcement action. See further information related to regulation by the FDA in Item 1A. Risk Factors.

All facilities where Rx and OTC drugs are manufactured, tested, packaged, stored or distributed must comply with FDA cGMPs and regulations promulgated by competent authorities in the countries where the facilities are located. All of the Company's drug products are manufactured, tested, packaged, stored and distributed according to cGMP regulations. The FDA performs periodic audits to ensure that the Company's facilities remain in compliance with all appropriate regulations. The failure of a facility to be in compliance may lead to a breach of representations made to store brand customers or to regulatory action against the Company related to the products made in that facility, including suspension of or delay in ANDA approvals, seizure, injunction or recall. Serious product quality concerns could also result in governmental actions against the Company that, among other things, could result in the suspension of production or distribution of the Company's products, product seizures, loss of certain licenses or other governmental penalties, and could have a material adverse effect on the Company's financial condition or operating results. In addition, several bills have been introduced in Congress that could, if enacted, affect the manufacture and marketing of Rx and OTC drugs. The Company cannot predict whether new legislation regulating the Company's activities will be enacted or what effect any legislation would have on the Company's business.

The Company submits a DMF for active pharmaceutical ingredients to be commercialized in the U.S. The DMF filings provide an efficient mechanism for FDA review while protecting the Company's proprietary information related to the manufacturing process. The manufacturing facilities are inspected by the FDA to assess cGMP compliance. The manufacturing facilities and production procedures utilized at the manufacturing facilities must meet current FDA Good Manufacturing Practice ("GMP") standards before products may be exported to the U.S. For European markets, the Company submits a European DMF and, where applicable, obtains a certificate of suitability from the European Directorate for the Quality of Medicines. The manufacturing facilities and production procedures for API marketed in Europe must meet EU-GMP and European Pharmacopeia standards.

Infant Formula. The FDA's Center for Food Safety and Applied Nutrition is responsible for the regulation of infant formula. The Office of Nutritional Products, Labeling and Dietary Supplements ("ONPLDS") has program responsibility for infant formula, while the Office of Food Additive Safety ("OFAS") has program responsibility for food ingredients and packaging. The ONPLDS evaluates whether the infant formula manufacturer has met the requirements under the FFDCA and consults with the OFAS regarding the safety of ingredients in infant formula and of packaging materials for infant formula.

All manufacturers of pediatric nutrition products must begin with safe food ingredients, which are either generally recognized as safe or approved as food additives. The specific requirements for infant formula are governed by the Formula Act. The purpose of the Formula Act is to ensure the safety and nutrition of infant formulas, including minimum, and in some cases, maximum levels of specified nutrients.

Once an infant formula product is formulated, the manufacturer must provide regulatory agencies assurance of the nutritional quality of that particular formulation before marketing the infant formula. The FDA has established requirements for certain labeling, nutrient content, and manufacturer quality control procedures (to assure the nutrient content of infant formulas), as well as for company records and reports. A manufacturer must notify the FDA 90 days before the marketing of any infant formula that differs fundamentally in processing or in composition from any previous formulation produced by the manufacturer. The FDA currently is finalizing revised good manufacturing practices, quality control procedures, quality factors, notification requirements, and reports and records, for the production of infant formulas. The Company is monitoring the situation and will make appropriate adjustments to remain in compliance.

In addition, as part of its responsibility to implement the provisions of the FFDCA, the FDA continuously monitors infant formula products. The FFDCA requires infant formula manufacturers to test product composition during production and shelf-life, to keep records on production, testing and distribution of each batch of infant formula and to use good manufacturing practices and quality control procedures. In addition, the FFDCA requires infant formula manufacturers to maintain records of all complaints, some of which are reviewed to reveal the possible existence of a health hazard. The FDA conducts yearly inspections of all facilities that manufacture infant formula. The FDA also inspects new facilities during early production runs. As part of the inspection, the FDA collects and analyzes samples of infant formula.

Dietary Supplements. The Dietary Supplement Health and Education Act of 1994 ("DSHEA") amended the FFDCA to, among other things: (1) define dietary supplements and dietary ingredients, (2) require ingredient and nutrition labeling for dietary supplements, (3) permit “structure/function” statements for dietary supplements, (4) permit the display of certain published literature where supplements are sold, (5) authorize the FDA to establish GMPs specifically for dietary supplements, and (6) require the submission of New Dietary Ingredient notification to the FDA.

The DSHEA provides specific nutrition labeling requirements for dietary supplements that are slightly different than those for conventional foods. All supplements must bear a “Supplement Facts” box, which must list all of the supplement’s dietary ingredients using nomenclature as specified in FDA regulations. DSHEA also permits dietary supplements to bear statements (1) claiming a benefit related to a classical nutrient deficiency disease, provided the prevalence of the disease in the U.S. is disclosed, (2) describing the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, (3) characterizing the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, and (4) describing general well-being from consumption of a nutrient or dietary ingredient. The Company is subject to regulations published by the FDA clarifying the types of “structure function” statements permissible in dietary supplement labeling. Such statements cannot expressly or implicitly state that a dietary supplement has any effect on a “disease.”

As with foods in general, dietary supplement labeling may include a “health claim,” which characterizes the role of a nutrient to a disease or health-related condition. There are two types of health claims: (1) health claims authorized by FDA regulations based on significant scientific agreement among qualified scientific experts, and (2) “qualified health claims,” which may be made with a lower level of substantiation, provided that the FDA does not object to the claims. In each case, the health claim must be reviewed and approved by the FDA before it may be used.

On June 25, 2007, the FDA issued Final GMP Regulations specific to Dietary Supplements, which became effective as they relate to the Company on June 25, 2008. The Company continues to invest in its Dietary Supplement operations to ensure compliance with the regulations. The FDA began inspecting the industry after the June 25, 2008 compliance date. The Company continuously monitors FDA activities, including publicly available inspection reports of other companies’ inspections, to ensure that its operations and quality systems are maintained in a state of compliance based on the current interpretation of the regulations. The Company has not yet been inspected and cannot determine with certainty what effects the FDA’s future interpretations of the regulations will have on its business. The GMP regulations and FDA’s future interpretations of these regulations could, among other things, require expanded documentation of the manufacturing processes for certain products or additional analytical testing for certain ingredients. In addition, several bills have been introduced in Congress that could, if enacted, affect the manufacture and marketing of dietary supplements. The Company cannot predict whether new legislation regulating the Company’s

activities will be enacted or what effect any legislation would have on the Company's business.

The DSHEA requires that the FDA be notified at least 75 days in advance of the introduction of a dietary supplement that contains a dietary ingredient that was introduced to market after October 15, 1994 or was present

in the food supply in a form where the food had not been chemically altered. The notification must provide information establishing that the dietary supplement containing the dietary ingredient will reasonably be expected to be safe.

U.S. Drug Enforcement Administration

The DEA regulates certain drug products containing controlled substances, such as morphine, hydromorphone, opium, and List I chemicals, such as pseudoephedrine, pursuant to the federal Controlled Substances Act ("CSA"). The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored and distributed, as well as yield losses. Companies handling either controlled substances or List I chemicals are also required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

The Company is subject to the requirements of the CSA and DEA regulations in the handling of any controlled substances in schedules II – V or any of the List I chemicals identified in the CSA. Specifically, the Company is subject to regulation in the commercial manufacture and distribution of products containing the List I drug pseudoephedrine and products containing the schedule II drugs morphine, hydromorphone and opium. As a result of a series of amendments to the CSA, the DEA has imposed increased restrictions on the manufacture and distribution of pseudoephedrine products. For example, the Comprehensive Methamphetamine Control Act of 1996 was enacted to authorize the DEA to monitor transactions involving chemicals that may be used illegally in the production of methamphetamine. The Comprehensive Methamphetamine Control Act of 1996 establishes certain registration and recordkeeping requirements for manufacturers of OTC cold, allergy, asthma and diet medicines that contain ephedrine, pseudoephedrine or phenylpropanolamine ("PPA"). While certain of the Company’s OTC drug products contain pseudoephedrine, which is a common ingredient in decongestant products, the Company’s U.S. products contain neither ephedrine nor PPA.

In addition, the Reauthorization Act of 2005, signed into law on March 9, 2006, prevented the existing provisions of the Patriot Act from expiring and also included the Combat Methamphetamine Epidemic Act. This law further amended the CSA and provided additional requirements with respect to the manufacture, distribution and sale of pseudoephedrine products. Among the various provisions, this national legislation places certain restrictions on the purchase and sale of all products that contain ephedrine, pseudoephedrine or PPA (List I chemical products). The CSA also imposed import and procurement quotas for List I chemicals, including pseudoephedrine.

The CSA, as amended, also imposed daily restrictions on the amount of List I chemical products a retailer may sell to a consumer (3.6 grams per day) and limitations on the amount of List I chemical products a consumer may purchase (9.0 grams) over a 30-day period. Further, effective September 30, 2006, the CSA requires that (a) retail sellers maintain a logbook that tracks the sales of List I chemical products to individuals, and (b) purchasers provide valid identification in order to purchase List I chemical products. Many states have also enacted legislation regulating the manufacture and distribution of pseudoephedrine products. The Company is subject to these state requirements as well.

Medicaid Drug Rebate Program and Other Drug Pricing Programs

Federal law requires that a pharmaceutical manufacturer, as a condition of having federal funds being made available to the states for the manufacturer’s drugs under Medicaid and Medicare Part B, must enter into a rebate agreement to pay rebates to state Medicaid programs for the manufacturer’s covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. The Centers for Medicare and Medicaid Services ("CMS") is responsible for administering the Medicaid rebate agreements between the federal government and pharmaceutical manufacturers. Rebates are due on the utilization of Medicaid managed care organizations, as well as under fee-for-service arrangements.

Drug manufacturers’ Medicaid rebate agreements, which are between each manufacturer and the Secretary of Health and Human Services, provide that the drug manufacturer will remit rebates to each state Medicaid agency on a

quarterly basis. Those rebates are based on pricing data reported by manufacturers to CMS, including Average Manufacturer Price ("AMP"), which is reported on a monthly and quarterly basis, and, in the case of innovator products, Best Price, which is reported on a quarterly basis. Health reform legislation changed the definition of AMP effective the fourth quarter of calendar 2010. Pursuant to the same legislation, effective for rebate

periods beginning with the first quarter of calendar 2010, the rebate formulas used to determine the minimum rebate amounts due are as follows: for noninnovator products, in general generic drugs marketed under ANDAs, the rebate amount is 13% of the AMP for the quarter; for innovator products, in general brand-name products marketed under NDAs, the rebate amount is the greater of 23.1% of the AMP for the quarter or the difference between such AMP and the Best Price for that same quarter. This rate is 17.1% for innovator drugs approved exclusively for pediatric indications, as well as for certain clotting factors. Manufacturers also pay an additional rebate on innovator drugs where price increases since launch have outpaced inflation.

The Company has a Medicaid rebate agreement in effect with the federal government. Federal and/or state governments have and are expected to continue to enact measures aimed at reducing the cost of drugs to such governmental payers as well as the public, including the enactment in December 2003 of Medicare legislation that expanded the scope of Medicare coverage to include outpatient drugs (Part D), starting in January 2006, as well as health reform legislation enacted in 2010. Management cannot predict the nature of such measures or their impact on the Company’s profitability. Various states have in recent years also adopted supplemental drug rebate programs that are intended to provide the individual states with additional manufacturer rebates on Medicaid utilization over and above those required under a manufacturer’s federal Medicaid agreement. States also have created drug coverage and corresponding manufacturer rebate programs for non-Medicaid populations, known as state pharmaceutical assistance programs. These rebate programs are generally designed to mimic the federal drug rebate program in terms of how the manufacturer rebates are calculated. Although there are a number of supplemental and state pharmacy assistance rebate programs, for the Company they are insignificant in the aggregate compared to quarterly Medicaid drug rebate obligations.

As described herein, CMS rules require pharmaceutical companies to calculate and report the AMP to CMS on a monthly as well as a quarterly basis. In addition to using this information to calculate rebates, CMS uses AMP to calculate a type of federal ceiling on reimbursement rates for multiple source drugs to pharmacies under the Medicaid program, known as the federal upper limit ("FUL"). Prior to using AMP, CMS typically used the Average Wholesaler Price ("AWP") or Wholesaler Acquisition Cost ("WAC") in the calculation of FULs. As discussed herein, health reform legislation enacted in 2010 amended the statutory definition of AMP and also amended the definition of "multiple source drug” in a manner that materially affects the calculation of FULs. CMS has begun posting draft FUL reimbursement files on the CMS website that are calculated based on the requirements of the health reform legislation. Currently, the FUL reimbursement files are for review and comment only; however, CMS has announced that it plans to publish final FULs after a period of releasing them in draft format. CMS issued a proposed rule in February 2012 that provided guidance on the revised AMP definition and calculation of FULs but has not issued a final rule. Separately, under existing statutory authority granted by the Deficit Reduction Act of 2005, CMS announced this year that it will begin collecting retail survey price information from retail community pharmacies to generate publicly available pricing files. CMS expects that the pricing files will provide state Medicaid agencies with an array of covered outpatient drug prices concerning retail pharmacy acquisition costs and consumer purchase prices and that state agencies can use this information to compare their own reimbursement and pricing methodologies and rates to those derived from the surveys. CMS has not yet begun posting this retail survey price information. The Company does not know how the new methodologies for calculating AMP and FULs or the retail survey price information will affect the Company's pharmacy customers or to what extent these customers will seek to pass on any decrease in Medicaid reimbursements to the Company. The Company cannot