PERRIGO CO
Form 10-K
August 18, 2009
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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 27, 2009

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	49010
Allegan, Michigan	(Zip Code)
(Address of principal executive offices)	

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 [ ] 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 26, 2008 as reported on The NASDAQ Global Select Market, was $2,558,803,687. 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, 2009, the registrant had 92,236,959 outstanding shares of common stock.

Documents incorporated by reference: Portions of the Registrant s Proxy Statement for its Annual Meeting of Shareholders on October 29, 2009 are incorporated by reference into Part III of this Form 10-K.

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PERRIGO COMPANY

FORM 10 K

FISCAL YEAR ENDED JUNE 27, 2009

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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 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, nutritional products, active pharmaceutical ingredients (API) and pharmaceutical and medical diagnostic products. The Company is the world s largest manufacturer of OTC pharmaceutical products for the store brand market. The Company s primary markets and locations of manufacturing and logistics operations are the United States (U.S.), Israel, Mexico and the United Kingdom (U.K.). See Note 17 to the Company s consolidated financial statements for further information.

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. (formerly J.B. Laboratories, Inc.) and Perrigo Florida, Inc. (formerly Unico Holdings, Inc.). 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, Brunel Pharma Limited (formerly Brunel Healthcare Ltd.) and Galpharm Healthcare Ltd. As used herein, references to the Company means 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 three reportable segments aligned primarily by type of product: Consumer Healthcare, Rx Pharmaceuticals and API. Additionally, 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. Due to the planned divestiture of the Israel Consumer Products business noted below, the Israel Pharmaceutical and Diagnostic Products operating segment represents the totality of the Other category.

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In March 2009, the Company committed to a plan to sell its Israel Consumer Products business. The financial results of this business, which were previously reported as part of the Company s Other category, have been recorded as discontinued operations in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. Accordingly, for all years presented, all consolidated statements of income information in this Annual Report on Form 10-K have been adjusted and the discontinued operations information is excluded unless otherwise noted.

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 business 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 includes the Company s U.S., U.K. and Mexico operations supporting the sale of OTC pharmaceutical and nutritional 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 analgesic, cough/cold/allergy/sinus, gastrointestinal, smoking cessation, first aid and vitamin and nutritional supplement 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. 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 a comparable national brand product.

Significant Developments

Acquisitions

On November 13, 2008, the Company acquired 100% of the outstanding shares of privately held Unico Holdings, Inc. (Unico) for $51,853 in cash. Based in Lake Worth, Florida, Unico was the leading manufacturer of store brand pediatric electrolytes, enemas and feminine hygiene products for retail customers in the U.S. The acquisition of Unico expands the Company s OTC product portfolio in the U.S. and is expected to add approximately $50,000 of annual sales. Unico s results of operations are recorded in the Company s Consumer Healthcare segment beginning in the Company s second quarter of fiscal 2009.

On October 6, 2008, the Company acquired 100% of the outstanding shares of privately held Laboratorios Diba, S.A. (Diba) for $24,500 in cash. Based in Guadalajara, Mexico, Diba was a store brand manufacturer of OTC and prescription pharmaceuticals, including antibiotics, hormonals and ophthalmics. The acquisition of Diba expands the Company s global presence and product portfolio in Mexico and is expected to add approximately $10,000 of annual sales. Diba s results of operations are recorded in the Company s Consumer Healthcare segment beginning in the Company s second quarter of fiscal 2009.

On September 16, 2008, the Company acquired J.B. Laboratories, Inc. (JBL), a privately held contract manufacturer of OTC and nutrition products for leading healthcare suppliers, for $43,605, including debt assumed. The acquisition of JBL provides additional FDA-compliant production capacity to help service current and future customer needs and is expected to add approximately $70,000 of annual sales. JBL s results of operations are recorded in the Company s Consumer Healthcare segment beginning in the Company s second quarter of fiscal 2009.

On June 18, 2008, the Company s U.K. subsidiary acquired the assets and related liabilities of Brunel Healthcare Ltd. (Brunel), a producer of OTC healthcare products, from NeutraHealth plc in exchange for the Company s net assets of its vitamins, minerals and supplements (VMS) business Perrigo U.K. Limited. Brunel s results of operations are recorded in the Company s Consumer Healthcare segment beginning in the Company s first quarter of fiscal 2009.

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In January 2008, the Company acquired 100% of the outstanding shares of privately held Galpharm Healthcare Ltd. (Galpharm) for $83,312. Galpharm was a leading supplier of OTC store brand pharmaceutical products sold by supermarkets, drug stores and pharmacies in the U.K. The acquisition of Galpharm expanded the Company s global presence and complements its existing U.K. business. Galpharm s results of operations are recorded in the Company s Consumer Healthcare segment beginning in the Company s third quarter of fiscal 2008.

In March 2007, the Company acquired the stock of Qualis, Inc., a privately owned manufacturer of store brand pediculicide products, for $12,401. The assets acquired consisted of the intangible assets attributable to the products acquired, which included primarily store brand OTC product formulations that compare to Rid® and Nix® brand products. The acquired assets expanded the Company s OTC product portfolio in the U.S. The transaction closed on July 3, 2007. Accordingly, the acquired assets and operating results related to these products are recorded in the Company s Consumer Healthcare segment beginning in the first quarter of fiscal 2008.

Consumer Healthcare Business

The Company is dedicated to being the leader in developing and marketing key 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 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 U.S. Food and Drug Administration (FDA), a process initiated by the drug innovator, through either its Abbreviated New Drug Application (ANDA) process or its New Drug Application (NDA) process. As part of its strategy, the Company relies on both internal development and strategic product development agreements with outside sources.

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 comparisons 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 Company currently markets over 1,300 store brand products, with over 11,000 SKUs, to over 900 customers. The Company considers every different combination of size, flavor and 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 name.

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Listed below are major Consumer Healthcare product categories under which the Company markets products for store brand labels; the annual retail market size for food, drug and mass merchandise retailers in the U.S., excluding Wal-Mart and those classified as club stores and dollar stores (according to Information Resources, Inc.); 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	$ 4.5	Advil® Cold & Sinus, Afrin®, Alavert®, Aleve® Cold & Sinus, Benadryl®, Claritin®, Dimetapp®, NyQuil®, DayQuil®, Robitussin®, Sudafed®, Tavist®, Triaminic®, Tylenol®, Zyrtec®
Dietary Supplements	$ 2.7	Centrum®, Flintstones®, One-A-Day®, Caltrate®, Pedialyte®, Osteo Bi-Flex®
Analgesics	$ 2.4	Advil®, Aleve®, Bayer®, Excedrin®, Motrin®, Tylenol®
Gastrointestinal	$ 2.4	Correctol®, Ex-Lax®, Fibercon®, Imodium A-D®, Maalox®, Mylanta®, Pepcid® AC, Pepto Bismol®, Phillips®, Tagamet HB®, Tums®, Zantac®, Prilosec OTC®
Smoking Cessation	$ 0.5	Nicorette®, Commit®

Customers of the Consumer Healthcare segment are major national and regional retail drug, supermarket and mass merchandise chains, such as Wal-Mart, CVS, Walgreens, Kroger, Safeway, Dollar General, Sam s Club and Costco, and major wholesalers, such as McKesson.

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 that are directly targeted 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 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. 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 products and categories and develop category management recommendations.

New Product Introductions and Drug Application Approvals

The Company launched several new products in fiscal 2009, most notably ibuprofen PM (nighttime sleep-aid) tablets and famotidine complete chewable tablets, which compete with the national brands Advil® PM tablets and Pepcid Complete® tablets, respectively. Net sales related to new products were approximately $328,100 for fiscal 2009, $191,300 for fiscal 2008 and $68,700 for fiscal 2007. A Consumer Healthcare product is considered new if it was added to the Company s product lines within 18 months prior to the end of the period for which net sales are being measured, unless otherwise noted.

In fiscal 2009, the Company, on its own or in conjunction with partners, received approval from the FDA for two OTC drug applications. The applications were for ibuprofen PM tablets and ibuprofen potassium softgel.

As of June 27, 2009, the Company, on its own or in conjunction with partners, has 16 OTC drug applications pending approval with the FDA.

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Competition

The market for OTC pharmaceutical and nutritional products is highly competitive. Competition is based primarily on 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. 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., Guardian Drug Company, LNK International, Inc., NBTY Inc. and Taro Pharmaceutical Industries Ltd. 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, competition is growing from generic prescription drug manufacturers that may market products requiring FDA approval or that have switched or are switching from Rx to OTC status. The Company competes in the nutritional 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 that of the Company.

PRESCRIPTION (Rx) PHARMACEUTICALS

The Rx Pharmaceuticals segment develops, manufactures and markets a portfolio of generic prescription drugs in the U.S. This portfolio is comprised of products within a broad array of topicals including creams, ointments, lotions, gels, shampoos, foams, suppositories, sprays, liquid suspensions and solutions.

Significant Developments

In November 2008, the Company acknowledged the settlement of patent litigation relating to a generic to Nasacort® AQ (triamcinolone acetonide nasal spray) product brought by Sanofi-Aventis against Teva Pharmaceutical Industries Ltd. (Teva) (formerly Barr Laboratories, Inc.), a partner with the Company for this product and the holder of the ANDA. The Company will share in the costs and benefits of the settlement agreement between Teva and Sanofi-Aventis and Teva s subsequent marketing of the product under the agreement, which will commence on June 15, 2011 or earlier in certain circumstances. In addition, the Company completed certain milestones with respect to the development of this product in the second fiscal quarter of 2009 resulting in recognizing revenue in the amount of $2,500. On July 31, 2009, Teva received FDA final approval for its ANDA. This event triggered additional future milestone payments for the Company that will result in a favorable impact going forward for the Rx Pharmaceuticals segment, but this impact is not considered to be significant to the Company s consolidated operating results.

License Agreement

In the third quarter of fiscal 2008, the Company s Israeli subsidiary and a customer agreed to terminate a license agreement. The termination agreement stated that the Company s Israeli subsidiary was to receive from the customer $8,500 in lieu of expected future minimum royalty payments. This amount was paid in full and recognized in net sales for the Rx Pharmaceuticals segment in the third quarter of fiscal 2008. As part of the Agis Industries (1983) Ltd. (Agis) acquisition in March 2005, the Company recorded an intangible asset related to this license agreement. In conjunction with the termination of the agreement, the Company wrote off the remaining net book value of $3,513 in the third quarter of fiscal 2008 as an acceleration of amortization expense.

Intangible Assets

The Company holds certain individual product-related intangible assets including, among others, those obtained from acquisitions. Whenever events or changes in circumstances indicate the carrying amount of any individual intangible asset may not be recoverable, the Company tests the asset for possible impairment. During the second half of fiscal 2008,

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additional competition entered the marketplace, exerting significant pressure on a certain product for which the Company holds a developed product formulation intangible asset. As a result, during the fourth quarter of fiscal 2008, the Company recorded an impairment charge of $10,346 within cost of sales in its Rx Pharmaceuticals segment for the write-down of the intangible asset associated with this product. The $10,346 represents the difference between the intangible asset s net carrying value and fair value as determined by a discounted cash flow analysis.

Acquisition

In March 2007, the Company acquired certain generic prescription dermatological products from Glades Pharmaceuticals, Inc. (Glades) for approximately $57,000 in cash plus $2,500 of consideration for future research and development collaborations. The operating results related to these products are included in the Company s consolidated results of operations beginning in the fourth quarter of fiscal 2007.

Rx Business

The Company develops, manufactures and markets primarily generic topical prescription pharmaceuticals. Topical products are manufactured at the Company s New York and Israel facilities and also sourced from various FDA-approved third parties. The Company also manufactures certain generic non-topical products at its Michigan facilities. The Company s current development areas include other delivery systems such as nasal sprays, oral liquids and transdermal products. Other areas of expertise include the production capabilities for various dosage forms such as tablets, capsules and liquids. Pharmaceuticals are manufactured, labeled and packaged in facilities that comply with strict regulatory standards, as well as meeting customers stringent requirements.

The Company currently markets approximately 250 generic prescription products, with over 600 SKUs, to approximately 110 customers. The Company includes as separate products multiple sizes and product forms of certain products. The Company generally holds the ANDA or NDA for the drugs that it manufactures or enters into an arrangement with the application holder for the manufacture and/or marketing of certain products.

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

Generic Name	Competitive Brand-Name Drug
Ammonium lactate cream and lotion	Lac-Hydrin®
Benzoyl peroxide gel	Benzac®
Cetirizine tablets and syrup	Zyrtec®
Clindamycin phosphate solution	CleocinT®
Clobetasol foam	Olux®
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®
Ketoconazole shampoo	Nizoral®
Mesalamine rectal suspension enema	Rowasa®
Mometasone cream, ointment and lotion	Elocon®
Mupirocin ointment	Bactroban®
Omeprazole tablets	Prilosec®
Permethrin cream	Elimite®
Salicylic acid shampoo	Salex®
Selenium sulfide shampoo	Selsun®
Sodium sulfacetamide wash	Ovace ®
Terconazole suppositories	Terazol 3®
Tretinoin cream and gel	Retin-A®

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The Company s U.S.-based customers are major wholesalers, such as Cardinal Health, McKesson and AmerisourceBergen, as well as national and regional retail drug, supermarket and mass merchandise chains, such as Walgreens, Wal-Mart, 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 prescription products, including hydroquinone 4% time release cream and 8% salicylic acid shampoo, which contain the same active ingredients present in the same dosage forms as Epiquin® and Salex® of SkinMedica and Valeant, respectively. Net sales related to new products were approximately $17,000 for fiscal 2009, $17,900 for fiscal 2008, and $6,500 for fiscal 2007. An Rx Pharmaceutical 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 2009, the Company received final approval from the FDA for one generic prescription drug application: sodium sulfacetamide lotion, 10%, therapeutically equivalent to Sanofi-Aventis Klaron®. As of June 27, 2009, the Company, on its own or in conjunction with partners, has 15 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 a particular product or group 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 related to collaboration agreements.

In April 2009, the Company entered into a joint development agreement with Medicis Pharmaceutical Corporation (Medicis). The agreement allows the Company to use its research and development know-how rights to develop a novel proprietary product. The Company recognized $840 in revenue during fiscal 2009 related to the agreement. The Company may recognize additional revenue related to the same agreement in the future if certain performance criteria are achieved. Further, the Company is entitled to receive royalty payments should Medicis begin selling the products being developed.

In October 2008, the Company entered into a licensing, manufacturing and supply agreement with Medimetriks Pharmaceuticals (Medimetriks). The Company owns certain intellectual property and know-how rights related to the following dermatology products: mupirocin ointment 2% (Centany®), urea 20% and ammonium lactate 12% foam (combination foam), urea 20% and ammonium lactate 12% medicated soap/wash (combination soap). Medimetriks has experience in selling and marketing dermatology products. The Company recognized $2,000 in revenue during fiscal 2009 related to the agreement with Medimetriks. The Company may recognize additional revenue related to the same agreement in the future if certain performance criteria are achieved. Further, the Company is entitled to receive royalty payments on sales of the products by Medimetriks.

In May 2008, the Company entered into a collaborative agreement with Cobrek Pharmaceuticals (Cobrek), a newly formed entity of Pentech Pharmaceuticals Inc. (Pentech), a privately owned company that specializes in the research and development of niche generic dosage forms. Pentech contributed its ANDA filing for a generic equivalent to Luxiq® foam, a $34,000 branded pharmaceutical product, to the agreement. The Company contributed two of its early stage generic topical pipeline products. One of the two pipeline products, a generic to Evoclin® foam, was submitted to the FDA in August 2008, with a Paragraph IV certification, and is currently subject to Hatch-Waxman patent litigation. This collaborative agreement was amended during fiscal 2009 to include two additional products. The Company recognized $1,450 of revenue related to the joint development of these two additional products in fiscal 2009. The parties will share the development costs and profits generated by these products, with the Company being the exclusive distributor of the collaboration products. Pentech contributed to Cobrek all of its interests in current and future ANDA filings, including a potential first-to-file on a generic version of Hectorol (doxercalciferol) injectable. The Company invested $12,500 in cash in Cobrek, accounted for on the cost method, in exchange for a minority, noncontrolling ownership position in the company.

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During fiscal 2006, the Company entered into a collaboration agreement with Cephalon Inc. (Cephalon) pursuant to which the parties have been collaborating on the development and manufacture of two drug products. The first product is a topical form of a proprietary Cephalon compound. The second product, which was identified and agreed upon by the parties in late 2006, is another topical form of that compound. The Company holds the authorized generic rights to the products, as well as the rights to manufacture the products for sale to Cephalon at a premium over its fully allocated manufacturing costs. As of June 27, 2009, the Company has received approximately $39,000 in total payments under this agreement. The revenues recognized under this agreement, which totaled $1,000, $13,300 and $20,000 in fiscal 2009, fiscal 2008 and fiscal 2007, respectively, are included within service and royalty revenues in the Rx Pharmaceuticals segment discussion included in Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations.

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 Actavis U.S., Fougera, Paddock Laboratories, Sandoz, Taro Pharmaceutical, Teva Pharmaceutical, and Triax 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 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 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, law suits, 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 that the first generic product is launched depriving the marketer of that generic product of the exclusivity intended by the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act (Hatch-Waxman). See Information Applicable to All Reported Segments Government Regulation U.S. Food and Drug Administration below.

Many of the Company s customers, which are chain drug stores, hospitals and hospital systems, wholesalers 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 and Germany.

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Significant Developments

In the fourth quarter of fiscal 2009, the Company determined that its German API facility was no longer competitive from a global cost position, and accordingly, the Company currently expects to cease all operations at the facility during the first quarter of fiscal 2011. In connection with the future closure of this facility, the Company incurred restructuring charges of $14,647 in its API segment, primarily related to employee termination benefits and asset impairments. Upon closure of the plant, the Company expects to incur costs of approximately $3,300 related to plant shut-down expenses.

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, an API manufacturing facility in India, for approximately $12,000 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 during fiscal 2011 and will include certain API products currently manufactured in Germany and Israel.

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. In fiscal year 2009, the Company recognized revenue of approximately $600 related to certain dossier agreements. The Company expects to continue to recognize revenue from these 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. An established position in the development and manufacture of API is increasingly important to the Company as a means 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 Pharmaceutical 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 Federal Trade Commission (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.

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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
Letrozole
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

New Product Introductions

During fiscal 2009, the Company launched several new APIs, including rocuronium bromide and cisatracurium. Net sales related to new products were approximately $4,900 for fiscal 2009. 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. Such competition may result in 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 consists 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 statements of income 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. See Note 3 of the Notes to Consolidated Financial Statements for additional information regarding discontinued operations.

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Competition

The Company s Other category operates in competitive markets. These markets are based primarily in Israel but are also subject to competition 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 the Consumer Healthcare markets focuses on products comparable in formulation, quality and effectiveness to existing national brand OTC products 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 $77,922 for fiscal 2009, $72,191 for fiscal 2008, and $66,480 for fiscal 2007. In addition, fiscal 2009 included a $279 charge for the write-off of in-process research and development related to the Diba acquisition, fiscal 2008 included a $2,786 charge for the write-off of in-process research and development related to the Galpharm acquisition, and fiscal 2007 included an $8,252 in-process research and development charge related to the Glades acquisition. The fiscal 2009 increase in research and development costs was due to increased investment in the development of new drugs, primarily in the Consumer Healthcare segment. The fiscal 2008 increase was due to an increase in the number of clinical trials and additional internal development activities, as well as the inclusion of ongoing research and development expenses related to Galpharm s operations during the second half of fiscal 2008. The Company anticipates that research and development expenditures, including legal costs associated with defending Paragraph IV patent litigation, will remain at or slightly above fiscal 2009 levels, 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 that its primary customer base aligns with the concentration of large drug retailers in the current marketplace of the retail drug industry. Wal-Mart accounted for 23% of consolidated net sales for fiscal 2009, 21% for fiscal 2008 and 22% for fiscal 2007. Should Wal-Mart 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. If the Company s relationship with one or more of these customers changes significantly, it could have a material adverse impact on the Company s financial position and results of operations.

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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 Germany along with a joint venture located in China. The Company supplements its production capabilities with the purchase of product from outside sources. During fiscal 2009, the approximate average capacity utilization was 85% and 70% for the Company s U.S. and Israeli facilities, respectively. The capacity of some facilities may be fully utilized at certain times due to various reasons, such as 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. and Mexico. 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 Rx Pharmaceuticals, API and Other segments are generally not impacted significantly by seasonal conditions.

Materials Sourcing

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 Rx Pharmaceuticals 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, the nature of the FDA restrictions placed on products approved through the ANDA or NDA process could substantially lengthen the approval process for 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 $74,800. 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.

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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 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 marketing of ANDA, NDA and OTC monograph drug products and the marketing of dietary supplement and medical food products, which are both regulated as foods. The FDA s jurisdiction extends to the manufacturing, testing, labeling, packaging, storage and distribution of these products.

OTC and Generic Prescription Pharmaceuticals. The majority of the Company s OTC pharmaceuticals are regulated under the OTC monograph system and subject to certain FDA regulations. OTC medicines, other than those approved by direct application, are marketed under regulations referred to as OTC monographs and have been established through the FDA s OTC drug review that follow 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 monograph system includes well-known ingredients and specifies 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 and labeling requirements; however, these products generally can be developed 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. 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. 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 ANDA process generally requires less time and expense for FDA approval than the NDA process. 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. This 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 clinical studies. Approval time currently averages 24 months from the date the ANDA is submitted. 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 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 could prevent other companies from obtaining approval of any ANDAs or certain other pending applications for the product. Unless the Company establishes relationships with the companies having exclusive marketing rights, or the Company conducts its own clinical trials, the Company s ability to market Rx to OTC switch

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products and offer its customers products comparable to the national brand products could be delayed if the three-year exclusivity is granted to the initiating company. There can be no assurance that, in the event the Company applies for FDA approvals, the Company will obtain the approvals to market Rx or Rx to OTC switch products or, alternatively, that the Company will be able to obtain these products from other manufacturers.

Under the Federal Food, Drug and Cosmetic Act, 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 for that product. When a company submits an ANDA, the company is required to include a patent certification to certain patents that cover 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. 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 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, most notably many of those acquired from Glades, 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 June 2006 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 unapproved drugs 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 in Item 1A. Risk Factors.

All facilities where Rx and OTC drugs are manufactured, tested, packaged, stored or distributed must comply with FDA cGMPs. All of the Company s ANDA, NDA and OTC 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 seizure, injunction or recall. 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 DMFs 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 FDA 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.

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Dietary Supplements. The Dietary Supplement Health and Education Act of 1994 (DSHEA) amended the Federal Food, Drug and Cosmetic Act 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, and (4) permit the display of certain published literature where supplements are sold.

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 neither marketed prior to October 15, 1994 nor 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.

DSHEA provides for 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 Good Manufacturing Practice (GMP) Regulations specific to Dietary Supplements, which became effective as it relates 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.

U.S. Drug Enforcement Administration

The DEA regulates certain drug products containing controlled substances, such as testosterone, 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. 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.

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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 current manufacture and distribution of products containing pseudoephedrine, a List I chemical. 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.

More recently, the Reauthorization Act of 2005 was signed into law on March 9, 2006. The Reauthorization Act of 2005 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 on the 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 production quotas for List I chemicals, including pseudoephedrine, which have limited the Company s ability to import and manufacture pseudoephedrine products.

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 Act 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.

Centers for Medicare and Medicaid Services

The Centers for Medicare and Medicaid Services (CMS) is responsible for administering the Medicaid rebate agreements between the federal government and pharmaceutical manufacturers. Such drug manufacturers agreements, which are between each manufacturer and the Secretary of Health and Human Services, provide that the drug manufacturer will remit to each state Medicaid agency, on a quarterly basis, the following rebates: for noninnovator products, in general generic drugs marketed under ANDAs, the rebate amount is 11% of the Average Manufacturer Price (AMP) for the quarter; for innovator products, in general brand-name products marketed under NDAs, the rebate amount is the greater of 15.1% of the AMP for the quarter or the difference between such AMP and the best price for that same quarter. An additional rebate for innovator products is payable in the amount by which, if any, the product s AMP has increased at a rate faster than 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 numerous health reform legislative proposals currently being considered at the federal level. 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.

The Deficit Reduction Act (DRA) of 2005 amended the Medicaid statute in a number of ways, including to revise the methodology for the calculation of federal upper limits, a type of cap on the amounts a state Medicaid program can reimburse pharmacies for drugs dispensed to Medicaid patients, as well as to require the public availability of AMP data.

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In July 2007, CMS issued a final rule regarding the calculation of AMP as well as these statutory amendments made by the DRA. This rule, as required by the DRA amendments, requires CMS to use AMP to calculate federal upper limits. Prior to the enactment of this legal requirement, CMS typically used the Average Wholesaler Price (AWP) or Wholesaler Acquisition Cost (WAC) in the calculation of federal upper limits. The rule also rejected requests to postpone the public availability of AMP data. In mid-December 2007, a preliminary injunction was granted, resulting in postponement of the actual implementation of these aspects of the DRA and the rule such that AMP currently cannot be used to calculate federal upper limits and also cannot be disclosed to the public. As of August 18, 2009, the relevant court case is still pending and the injunction remains in place, resulting in a continual postponement of the implementation of these requirements. In addition to this injunction, on July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) became law. The law provides that no AMP data will be made available to the public prior to October 2009 and also postpones implementation of the rule s AMP-based federal upper limits until October 2009. The Company does not know how the new methodology for calculating federal upper limits, if implemented, 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. It is also unknown how MIPPA will impact consumers access to generic medicines, which could significantly affect the market for these products. The Company cannot predict how the sharing of manufacturer-specific data may impact competition in the marketplace. Current legislative proposals in Congress also could impact these issues.

Additional Federal and State Regulation

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical device industries in recent years. These laws include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company s marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines, and imprisonment.

Consumer Product Safety Commission

Under the Poison Prevention Packaging Act (PPPA), the CPSC has authority to designate that dietary supplements and pharmaceuticals require child resistant packaging to help reduce the incidence of accidental poisonings. The CPSC has published regulations requiring iron-containing dietary supplements and numerous pharmaceuticals to have child resistant packaging, and has established rules for testing the effectiveness of child resistant packaging and for ensuring senior adult effectiveness.

The Consumer Product Safety Improvement Act of 2008 (CPISA) amended the Consumer Product Safety Act (CPSA) to require that the manufacturer of any product that is subject to any CPSC rule, ban, standard, or regulation certify that

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based on a reasonable testing program the product complies with such requirements. This certification applies to pharmaceuticals and dietary supplements that require child-resistant packaging under the PPPA. The CPSC has issued a stay of enforcement of the certification requirement until February 9, 2010.

Federal Trade Commission

The FTC exercises primary jurisdiction over the advertising and other promotional practices of marketers of dietary supplements and OTC pharmaceuticals and often works with the FDA regarding these practices. The FTC considers whether a product s claims are substantiated, truthful and not misleading. The FTC is also responsible for reviewing mergers between pharmaceutical companies exceeding specified thresholds and investigating certain business practices relevant to the healthcare industry. For example, in accordance with the Medicare Prescription Drug Improvement and Modernization Act of 2003, agreements between NDA and ANDA holders relating to settlements of patent litigation involving paragraph IV certifications under the Hatch-Waxman Act, as well as agreements between generic applicants that have submitted ANDAs containing paragraph IV certifications where the agreement concerns either company s 180-day exclusivity, must be submitted to the FTC (and the United States Department of Justice) for review. The FTC could challenge these business practices in administrative or judicial proceedings.

State Regulation

Most states regulate foods and drugs under laws that generally parallel federal statutes. The Company is also subject to other state consumer health and safety regulations that could have a potential impact on the Company s business if the Company is ever found to be non-compliant. Additionally, logistics facilities that distribute generic prescription drugs are required to be registered within each state. License requirements and fees vary by state.

United States Pharmacopeial Convention

The USP is a non-governmental, standard-setting organization. By reference, the Federal Food, Drug and Cosmetic Act incorporates the USP quality standards and monographs as the standards that must be met for the listed drugs, unless compliance with those standards is specifically disclaimed. USP standards exist for most Rx and OTC pharmaceuticals and many nutritional supplements. The FDA typically requires USP compliance as part of cGMP compliance.

NSF International

NSF is an independent, not-for-profit, non-governmental organization providing risk management services for public health and safety. Its services include standards development, product certification, safety audits, management systems registration and education programs. NSF is accredited by the American National Standards Institute, the Occupational Safety and Health Administration and the Standards Council of Canada. These accreditations attest to the competency of services provided by NSF and compliance with established national and international standards for third-party certification.

The NSF Dietary Supplement Certification Program enables manufacturers to become independently registered by NSF as conforming to voluntary standards that provide a system of processes, procedures and documentation to assure the product produced has the strength, composition, quality and purity represented on the product label. The Company s facilities making dietary supplements have earned NSF GMP registration. The Company also has approximately 66 store brand products certified under NSF/ANSI Standard 173 for dietary supplement products.

Foreign Regulation

The Company, through its affiliates located in the U.K., manufactures, packages and distributes OTC pharmaceuticals and provides contract manufacturing and packaging services for major pharmaceutical and healthcare companies in the U.K. and for export to markets outside the U.K. The manufacturing, processing, formulation, packaging, testing, labeling, advertising and sale of these products are subject to regulation by one or more U.K. agencies, including the Medicines and Healthcare Products Regulatory Agency, the Department of Health, the Department of the Environment, Her Majesty s Customs and Excise, the Department of Trade and Industry, the Health and Safety Executive and the Department of Transport.

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The Company manufactures, packages and distributes Rx pharmaceutical, OTC pharmaceutical and nutritional products in Mexico. The manufacturing, processing, formulation, packaging, labeling, testing, advertising and sale of these products are subject to regulation by one or more Mexican agencies, including the Health Ministry, the Commercial and Industrial Secretariat, the Federal Work s Secretariat, the Environmental Natural Resources and Fishing Secretariat, the Federal Environmental Protection Ministry, and the Treasury and Public Credit Secretariat and its Customs Government department.

The Company exports OTC pharmaceutical and nutritional products to foreign countries. Exporting requirements are regulated by the FDA and where appropriate, DEA laws, as well as each individual country s requirements for importation of such products. Each country requires approval of these products through a registration process by that country s regulatory agencies. Registration requirements include the process, formula, packaging, testing, labeling, advertising and marketing of the products. Each country regulates what is required and may be represented to the public on labeling and promotional material. Approval for the sale of the Company s products by foreign regulatory agencies may be subject to delays.

In Europe and Israel, the manufacture and sale of pharmaceutical products are regulated in a manner similar in many respects to that in the U.S. Legal requirements generally prohibit the handling, manufacture, marketing and importation of any pharmaceutical product unless it is properly registered in accordance with applicable law. The registration file relating to any particular product must contain medical data related to product efficacy and safety, including results of clinical testing and references to medical publications, as well as detailed information regarding production methods and quality control. Health ministries are authorized to cancel the registration of a product if it is found to be harmful or ineffective or manufactured and marketed other than in accordance with registration conditions. Data exclusivity provisions exist in many countries, including in the European Union, where these provisions were recently extended, although the application is not uniform. Similar provisions may be adopted by additional countries, including Israel, where legislation has been proposed. In general, these exclusivity provisions prevent the approval and/or submission of generic drug applications to the health authorities for a fixed period of time following the first approval of the brand-name product in that country. As these exclusivity provisions operate independently of patent exclusivity, they may prevent the submission of generic drug applications for some products even after the patent protection has expired.

Conditions in Israel

The Company s Israeli operations, which include manufacturing and research and development, are subject to Israeli law. Political, economic and military conditions in Israel directly affect the Company s operations and the Company could be adversely affected by hostilities involving Israel or a significant recession or downturn in the economic or financial condition of Israel. See Item 1A. Risk Factors Conditions in Israel for further information.

Employees

As of August 10, 2009, the Company had approximately 7,250 full-time and temporary employees worldwide, who were located as follows:

Country	Total Number of Employees	Number of Employees Covered by Collective Bargaining Agreements
U.S.	4,200	250
Israel	1,650	450
Mexico	800	400
U.K.	500	-
Rest of the world	100	85

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Item 1A. Risk Factors. (Dollar amounts in thousands)

Regulatory Environment

Several U.S. and foreign agencies regulate the manufacturing, processing, formulation, packaging, labeling, testing, storing, distribution, advertising and sale of the Company s products. Various state and local agencies also regulate these activities. In addition, the Company manufactures and markets certain of its products in accordance with the guidelines established by voluntary standards organizations. Should the Company or one of its third party service providers used in the development or commercialization of product fail to adequately conform to these regulations and guidelines, there may be a material adverse impact on the operating results of the Company. In particular, packaging, labeling or marketing changes mandated by the FDA or state and local agencies can have a material adverse impact on the results of operations of the Company. Required changes could be related to safety or efficacy issues. Similarly, the failure by the Company or one of its suppliers to comply with manufacturing, quality and testing guidelines and regulations could have a significant adverse impact on the Company s operating results. There is also the risk that the FDA could require the Company to audit or repeat prior bioequivalence or clinical studies or the FDA could change or withdraw the approval governing such products, which could have a material adverse impact on the results of the Company s operations. The Company believes that it has a good relationship with the FDA, which it intends to maintain. If these relationships should deteriorate, however, the Company s ability to bring new and current products to market could be impeded. See Item 1. Business Government Regulation.

The FDA s policy regarding the award of a 180-day market exclusivity period to generic manufacturers who successfully challenge patents relating to specific products continues to be the subject of extensive litigation in the U.S. The FDA s current interpretation of Hatch-Waxman is to award 180 days of exclusivity to the first generic manufacturer who files a successful paragraph IV certification under Hatch-Waxman challenging the patent of the branded product, regardless of whether the manufacturer was sued for patent infringement. Although the FDA s interpretation may benefit some of the products in the Company s pipeline, it may adversely affect others. The Medicare Prescription Drug Improvement and Modernization Act of 2003 provides that the 180-day market exclusivity period provided under Hatch-Waxman is triggered by the commercial marketing of the product. However, the Medicare Prescription Drug Act also contains forfeiture provisions which, if met, will deprive the first paragraph IV filer of exclusivity. Additionally, the manufacturer of the branded product may launch a generic version of its own drug, known as an authorized generic. Under certain circumstances, the Company may not be able to fully exploit its 180-day exclusivity period resulting from it being the first filer.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted into law. This law gives the FDA new powers to restrict medications that raise serious safety concerns. This law requires, and provides funding for, the FDA to monitor drugs after they go on the market. In addition, this law requires companies to make public the results of many of their studies. Under this new law, the FDA has the authority to require new studies, limit distribution or order label changes. Because of this law, the Company s ability to bring new and current products to market could be impeded, which could have a negative material impact on the Company s financial position or results of operations.

The Company s prescription drug products that are marketed without approved applications, most notably many of those acquired from Glades, 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 June 2006 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 unapproved drugs 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. The Company believes that so long as it complies with applicable manufacturing and labeling standards it will be consistent with the FDA s current enforcement policy. There can be no assurance that the FDA will continue this policy or not take a contrary position with any individual product or group of products. If the FDA were to do so, the Company may be required to seek FDA approval for these products or withdraw such products from the market. For fiscal 2009, the Company s annual sales for such unapproved products were approximately $14,000.

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The FDA held a public meeting on November 14, 2007 to explore the public health benefit of creating a new Behind-The-Counter (BTC) class of drugs. Drugs placed in this category would be available without a prescription, but only after intervention by a pharmacist. It is not known at this time what, if any, action the FDA will take in response to this issue. Certain actions by the FDA, such as moving certain OTC products to BTC, could have a material adverse effect on the operating results of the Company.

All facilities where Rx and OTC drugs are manufactured, tested, packaged, stored or distributed must comply with FDA cGMPs. All of the Company s ANDA, NDA and OTC drug products are manufactured, tested, packaged, stored and distributed according to cGMP regulations. Effective June 25, 2008, all facilities where dietary supplements are manufactured, tested, packaged, stored or distributed must comply with the GMP regulations for dietary supplements published in the Federal Register on June 25, 2007. 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 seizure, injunction or recall, and could have a material adverse effect on the Company s financial condition or operating results.

Acetaminophen

The Company manufactures several products that contain the active ingredient acetaminophen, which is indicated as an analgesic. On June 29 and 30, 2009, the FDA held a public advisory committee meeting to discuss how to address the potential for liver injury related to the risk of overdose of acetaminophen in both OTC and Rx products. The FDA expressly stated that it is not seeking to remove acetaminophen from the market and that the risk of developing liver injury to the individual patient who uses the drug according to directions is extremely low. However, due to the extensive use of acetaminophen-containing products, the FDA sought guidance from several advisory committees regarding measures to reduce the potential for liver injury associated with acetaminophen use. Measures discussed include, but were not limited to, reducing the maximum single-dose and daily-dose, reducing packaging sizes, and increase consumer educational efforts regarding such products. The FDA is reviewing the input it received from the advisory committees and is keeping the docket open until September 30, 2009 to receive additional comments. In fiscal 2009, products containing acetaminophen generated revenues of approximately $143,000 for the Company. The Company cannot predict whether the FDA will adopt any recommendations of the advisory committees regarding the sale and use of acetaminophen or whether any such recommendations, if adopted by the FDA, would impact future revenues attributable to these products.

Pediatric Cough-Cold Medications

In October 2007, the FDA convened a joint meeting of the Pediatric and Non-Prescription Drugs Advisory committees to discuss the safety and efficacy of OTC cough and cold products for use in children. The advisory committees recommended that these products no longer be used in children under the age of six. In January 2008, the FDA issued a Public Health Advisory recommending against the use of OTC cough and cold products in children under two years of age and announced that the FDA planned to issue recommendations in the second quarter of 2008 with respect to the use of OTC cough and cold products in children two through eleven years of age. The FDA had also indicated that the recommendations could include removing pediatric cough and cold products from the marketplace altogether by issuing a proposed rule recommending OTC cough and cold products for children under twelve generally not be recognized as safe and effective. On October 8, 2008, the FDA issued a statement supporting the voluntary action of the Consumer Healthcare Product Association (CHPA), of which the Company is a member, to modify product labels for consumers of OTC cough and cold medicines to state do not use in children under four years of age. Sales of the Company s pediatric cough and cold products could be adversely affected by such recommendations.

Pseudoephedrine

The Company produces a number of products that contain the active ingredient pseudoephedrine (PSE), which is indicated as a decongestant. PSE has been under scrutiny as an ingredient illegally used to create methamphetamine. To address this concern, legislation has been enacted at the federal level over the past few years to place restrictions on the sales of PSE products (i.e., Combat Methamphetamine Epidemic Act) and authorizing the DEA to place quotas on the amounts of PSE products that can be manufactured (i.e., the Controlled Substances Act). At the state level, a number of

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states have introduced or passed legislation placing additional restrictions on the sale of PSE products. In addition, in 2006, the State of Oregon moved PSE products to prescription (Rx) status; since then, at least one other city (Washington, Missouri) has passed similar legislation and a few other states have considered moving PSE products to Rx status. Sales of PSE products by the Company in fiscal year 2009 were approximately $24,000. Sales of PSE products could be adversely affected by action at the state or federal level to place additional restrictions on the sale of PSE products.

Several Arkansas counties, led by and including Independence County, filed a lawsuit against the Company and various manufacturers and distributors of products containing PSE, which can be used to produce methamphetamine, an illegal drug. Through this lawsuit, the plaintiff counties sought to recoup as damages some of the expenses they have incurred to combat methamphetamine use and addiction. They also sought punitive damages, disgorgement of profits and attorneys fees. On February 11, 2008, the court granted defendants motion for summary judgment and dismissed this case with prejudice. On January 5, 2009, the Eighth Circuit Court of Appeals affirmed the prior district court order and dismissed the case with prejudice. Plaintiffs did not appeal this decision.

Phenylephrine

The Non-Prescription Drug Advisory Committee met on December 14, 2007 to discuss the efficacy of phenylephrine, an active ingredient used in various cough and cold products as a decongestant. The advisory committee vote recommended that available data is supportive of the efficacy of phenylephrine at 10 milligrams. In addition, the advisory committee recommended additional supporting evidence to assess the efficacy of a 10 milligram dose of phenylephrine. The recommendations by the advisory committee are not binding on the FDA. It is not known at this time what, if any, further action the FDA or industry will take in response to recommendations of the advisory committee. In fiscal 2009, products containing phenylephrine generated revenues of approximately $64,000. Certain actions by the FDA, such as mandating label and packaging changes, could have an adverse effect on the operating results of the Company.

Dextromethorphan

The Company manufactures several products that contain the active ingredient dextromethorphan, which is indicated for cough suppression. Dextromethorphan has come under scrutiny because of its potential to be abused. Some states have introduced legislation that, if passed, could require restricted access to dextromethorphan in finished dosage forms. Such legislation placing age restrictions on the purchase of OTC products containing dextromethorphan was passed at the local level by Suffolk County, New York, Westchester County, New York and by the City of Jerseyville, Illinois. At least one state has passed legislation restricting the bulk sale of dextromethorphan.

In March 2009, the Dextromethorphan Abuse Reduction Act of 2009 (H.R. 1259) was approved by the U.S. House of Representatives. This legislation, if enacted, would generally prohibit the bulk sale of dextromethorphan. A similar bill (S.1383) was introduced by Senator Durbin that would also impose a federal age limit of 18 years old in order to purchase finished products containing dextromethorphan. At the state level, in fiscal year 2009, a number of states introduced legislation to impose similar age restrictions on purchases of dextromethorphan in finished dosages. However, no such legislation has yet been adopted by a state. It is possible that any of the states or the federal government could introduce and pass legislation imposing additional or different restrictions on the sale of dextromethorphan in finished dosage form, such as requiring a minimum age to purchase product. In fiscal 2009, products containing dextromethorphan generated revenues of approximately $79,000. The Company cannot predict whether any of the proposed legislation will be passed or, if it is passed, its impact on future revenues attributable to these products.

Product Issues Effect of Misuse and Publicity

The Company s products are safe and effective when used in accordance with label directions. However, certain products contain ingredients that can be, and in some cases are, used for improper purposes. As previously discussed, pseudoephedrine and dextromethorphan are two of these ingredients, but others may exist. Increasingly, various efforts are employed by federal and state governments in an effort to curb this misuse, including the consideration of additional legislation or regulation that may result in further restrictive requirements for the manufacture or sale of products containing these ingredients. The Company cannot predict if or when any additional legislation or regulation will be approved. If this type of additional legislation or regulation is approved, it could have an adverse impact on the Company s results of operations.

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The Company believes that growth in the nutritional products business is based largely on national media attention regarding scientific research suggesting potential health benefits from regular consumption of certain vitamin and other nutritional products. There can be no assurance of future favorable scientific results and media attention, or the absence of unfavorable or inconsistent findings. In the event of future unfavorable scientific results or media attention, the Company s sales of nutritional products could be materially adversely impacted.

Healthcare and Legal Reforms

Increasing expenditures for healthcare have been the subject of considerable public attention in North America, Israel and many European countries. Both private and governmental entities are seeking ways to reduce or contain healthcare costs. In many countries in which the Company currently operates, pharmaceutical prices are subject to regulation. In the U.S., numerous proposals that would effect changes in the U.S. healthcare system and the pharmaceutical industry have been introduced or proposed in Congress and in some state legislatures that could include, but not be limited to, intellectual property, regulatory, antitrust, drug pricing and product liability issues. Similar activities are taking place throughout Europe. As a result of governmental budgetary constraints, the Israel Ministry of Health and the major Israeli health funds have sought to further reduce healthcare costs by, among other things, applying continuous pressure to reduce pharmaceutical prices and inventory levels. The Company cannot predict the nature of the measures that may be adopted, how they will be interpreted by the courts or the administrative agencies charged with enforcing them or their impact on the marketing, pricing and demand for its products.

In July 2007, the CMS issued a final rule for the calculation of the AMP, which pharmaceutical companies are required to report to the CMS. The CMS intends to use this calculation to help determine reimbursements to pharmacies that dispense medicines to Medicaid beneficiaries. Prior to this ruling, the CMS used the AWP in the calculation of the reimbursement. Additionally, the CMS has decided to publish manufacturer-specific AMP data. In mid-December 2007, a preliminary injunction was granted, resulting in postponement of the actual implementation of the rule. As of August 18, 2009, the relevant court case is still pending, resulting in a continual postponement of the rule. On July 15, 2008, MIPPA became law. The law provides that no AMP data will be made available to the public prior to October 2009. The Company does not know how the new reimbursement model will affect the Company s pharmacy customers or to what extent these customers will seek to pass on any increased Medicaid costs to the Company. It is also unknown how MIPPA will impact consumers access to generic medicines, which could significantly affect the market for these products. The Company cannot predict how the sharing of manufacturer-specific data may impact competition in the marketplace.

On July 14, 2009, Rep. Dingell introduced America s Affordable Health Choices Act (H.R. 3200). As approved by the Committee on Ways and Means, this legislation would eliminate the ability of American families to use funds from flexible spending accounts (FSAs) to purchase OTC medicines. The Company cannot predict how the elimination of allowing families to use FSA s to purchase OTC medicines would affect the market for OTC products.

Commercialization of New Products / Research and Development

The Company s future results of operations depend, to a significant degree, upon its ability to successfully commercialize additional OTC and generic drugs and/or innovative pharmaceuticals and API. The Company must develop, test and manufacture generic prescription products as well as prove that its generic prescription products are bioequivalent to their branded counterparts, which often requires bioequivalency studies or even more extensive clinical trials in the case of topical products. OTC drugs may require bioequivalency studies as well. All major products must meet regulatory standards and receive regulatory approvals. The development and commercialization process, particularly with respect to innovative products, is both time consuming and costly and involves a high degree of business risk. Products currently under development, if and when fully developed and tested, may not perform as expected, may be the subject of intellectual property challenges, necessary regulatory approvals may not be obtained in a timely manner, if at all, and the Company may not be able to successfully and profitably produce and market such products. Delays in any part of the process or the Company s inability to obtain regulatory approval of its products (including products developed by others to which the Company has exclusive marketing rights) could adversely affect operating results by restricting or delaying its introduction of new products. Even upon the successful development of a product, the Company s customer s failure to launch a product could adversely affect operating results. Continuous introductions of new products and product categories are critical to the Company s business. Product margins may decline over time due to the products aging life

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cycles, changes in consumer choice or developments in drug delivery technology. Therefore, new product introductions are necessary for maintenance of the Company s current financial condition, and if the Company fails to introduce and market new products, the effect on its financial results could be materially adverse.

The Company s investment in research and development is expected to remain at or slightly above recent levels, as a percentage of sales, due to the Company s ongoing broadening of its OTC ANDA, topical generic Rx and specialty API product portfolio, as well as several opportunities for new products that are switching from prescription to OTC status. The ability to attract scientists proficient in emerging delivery forms and/or contracting with a third party innovator in order to generate new products of this type is a critical element of the Company s long-term plans. Should the Company fail to attract qualified employees, successfully develop products in a timely manner, or enter into reasonable agreements with third parties, long-term sales growth and profit would be adversely impacted.

Potential Volatility of Stock Price

The market price of the Company s common stock has been, and could be, subject to wide fluctuations in response to, among other things, quarterly fluctuations in operating results, adverse circumstances affecting the introduction or market acceptance of new products, product recalls, failure to meet published estimates of or changes in earnings estimates by securities analysts, announcements of new products or enhancements by competitors, receipt of regulatory approvals by competitors, sales of common stock by existing holders, loss of key personnel, market conditions in the industry, shortages of key product inventory components and general economic conditions.

Fluctuation in Quarterly Results

The Company s quarterly operating results depend on a variety of factors including, but not limited to, the severity, length and timing of the cough/cold/flu season, the timing of new product approvals and introductions by the Company and its competitors, price competition, the magnitude and timing of research and development investments, changes in the levels of inventories maintained by the Company s customers and the timing of retailer promotional programs. Accordingly, the Company may be subject to significant and unanticipated quarter-to-quarter fluctuations.

Competitive Issues

The markets for OTC pharmaceutical, nutritional, generic pharmaceutical and API products are highly competitive. Competition is based primarily on price, quality and assortment of products, customer service, marketing support and availability of new products. Competition also comes from national brand companies and brand pharmaceutical companies. That competition could be intensified should those companies lower prices or manufacture their own store brand or generic equivalent products. Due to the high degree of price competition, the Company has not always been able to fully pass on cost increases to its customers. The inability to pass on future cost increases, the impact of store brand competitors and the impact of national brand companies lowering prices of their products or operating in the store brand market could have a material adverse impact on financial results. In addition, since the Company sells its nutritional products through retail drug, supermarket and mass merchandise chains, it may experience increased competition in its nutritional products business through alternative channels such as health food stores, direct mail and direct sales as more consumers obtain products through these channels. The Company has evaluated, and will continue to evaluate, the products and product categories in which it does business. Future product line extensions, or deletions, could have a material impact on the Company s financial position or results of operations.

Selling prices of generic drugs typically decline, sometimes dramatically, as competition intensifies due to additional companies receiving approvals for a given product or brands launching authorized generics. To the extent that the Company succeeds in being the first to market a generic version of a significant product, the Company s sales and profit can be substantially increased in the period following the introduction of such product and prior to a competitor s introduction of an equivalent product. The Company s ability to sustain its sales and profitability on any product over time is dependent on both the number of new competitors for such product, some of whom may be significantly larger than the Company, and the timing of their approvals.

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Certain competitors are choosing to consolidate in the generic pharmaceutical and nutritional industries. These consolidations may create larger companies with which the Company must compete and provide further pressure on prices, development activities or customer retention. The impact of future consolidation in the industry could have a material impact on the Company s financial position or results of operations.

The Company s API business is subject to increased competition from other manufacturers of API located in Europe and developing countries, such as India and China. Such competition may result in loss of API customers and/or decreased profitability in this business segment.

Store Brand Product Growth

The future growth of domestic store brand products will be influenced, in part, by general economic conditions, which can influence consumers to switch to and from store brand products, consumer perception and acceptance of the quality of the products available, the development of new products and/or product delivery forms, the market exclusivity periods awarded on Rx to OTC switch products and the ongoing or growing strength of the retailers brands in the market. The Company does not advertise like the national brand companies and thus is dependent on retailer promotional spending to drive sales volume and increase market share. Growth opportunities for the products in which the Company currently has a significant store brand market share (cough/cold/flu/allergy, analgesic, smoking cessation and gastrointestinal products) will be driven by the ability to offer new products to existing domestic customers. Branded pharmaceutical companies may use state and federal regulatory and legislative means to limit the availability of brand equivalent products. Should store brand growth be limited by any of these factors, there could be a significant adverse impact on the operating results of the Company.

Source of Raw Materials and Supplies

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. Supplies of certain raw materials, bulk tablets and finished goods purchased by the Company are limited, or are available from one or only a few suppliers. In such situations, increased prices, rationing and shortages can occur. In response to these problems the Company tries to identify alternative materials or suppliers for such raw materials, bulk tablets and finished goods. The nature of FDA restrictions placed on products approved through the ANDA or NDA process could substantially lengthen the approval process for an alternate material source. Certain material shortages and approval of alternate sources could adversely affect financial results. The rapid increase in cost of many raw materials from inflationary forces, such as increased energy costs, and the Company s ability or inability to pass on these increases to its customers, could have a material impact on the Company s financial results.

In addition, raw materials purchased from third parties, including those from foreign countries, may contain counterfeit ingredients or other adulterants. The Company maintains a strict program of verification and product testing throughout the ingredient sourcing and manufacturing process to identify counterfeit ingredients, adulterants and toxic substances. Nevertheless, discovery of previously unknown problems with the raw materials or product manufacturing processes or new data suggesting an unacceptable safety risk associated therewith, could result in a voluntary or mandatory withdrawal of the contaminated product from the marketplace, either temporarily or permanently. Any future recall or removal would result in additional costs to the Company, and may give rise to product liability litigation, either of which may have a material adverse effect on the operating results of the Company.

Legal Exposure

From time to time, the Company and/or its subsidiaries become involved in lawsuits arising from various commercial matters, including, but not limited to, competitive issues, contract issues, intellectual property matters, workers compensation, product liability, environmental remediation issues and state or federal regulatory issues. See Item 3 Legal Proceedings. Litigation is unpredictable and can be costly. No assurance can be made that litigation will not have a material adverse effect on the Company s financial position or results of operations in the future. Similarly, judicial decisions in proceedings to which the Company is not a party may result in the setting of legal precedent that could affect the future operation of the Company s business. In addition, the Company may face environmental exposures including,

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for example, those relating to discharges from and materials handled as part of its operations, the remediation of soil and groundwater contaminated hazardous substances or wastes, and the health and safety of its employees. While the Company does not have any material remediation liabilities currently outstanding, the Company may in the future face liability for the costs of investigation, removal or remediation of certain hazardous substances or petroleum products on, under, or in its currently or formerly owned property, or from a third party disposal facility that it may have used, without regard to whether the Company knew of, or caused, the presence of the contaminants. The actual or alleged presence of, or failure to remediate properly, these substances could have adverse effects, including, for example, substantial investigative or remedial obligations and limitations on the ability to sell or rent affected property or to borrow funds using affected property as collateral. There can be no assurance that environmental liabilities and costs will not have a material adverse effect on the Company s financial position, results of operations or cash flows.

Tax Law Implications

Income tax rate changes by governments and changes in the tax jurisdictions in which the Company operates could influence the effective tax rates for future years. Entry into new tax jurisdictions, whether domestic or international, increases the likelihood of fluctuation. The mix of income between tax jurisdictions in any given quarter can also significantly change the effective tax rate across quarters and years. In addition, changes in tax laws could have a material adverse effect on the Company s ability to utilize cash in a tax efficient manner.

Customer Issues

Sales to the Company s largest customer, Wal-Mart, comprised approximately 23% of fiscal 2009 net sales. Should Wal-Mart s current relationship with the Company change adversely, the resulting loss of business could have a material adverse impact on the Company s financial position and results of operations. In addition, while no other customer individually comprises more than 10% of total net sales, the Company does have other significant customers. If the Company s relationship with one or more of these customers changes significantly, it could have a material adverse impact on the Company s financial position and results of operations.

Maintaining the supply relationships with the Company s customers is critical to its success. If the Company is unable to deliver to expected customer service levels, customers may choose to assess penalties, obtain alternate sources for products, withhold new product introductions and/or end the relationship with the Company. The success in recent years of private label marketing programs has increased large retailers attention to the importance of their store brand programs and as a result, many are dedicating significant resources to auditing supplier compliance with their quality, ethical and service standards. Customers may limit the level of product sourcing with the Company in protection of the customer s own interests. Any or all of these factors could have a material adverse impact on the Company s financial position and results of operations.

Retailer consolidation could have an adverse impact on future sales growth. If a large customer should encounter financial difficulties, the Company s exposure on uncollectible receivables and unusable inventory, as well as the potential loss of future sales, could result in a material adverse impact on the Company s financial position or results of operations.

Conditions in Israel

The Company has significant manufacturing and research and development facilities in Israel. Political, economic and military conditions in Israel directly affect the Company s operations, and the Company could be adversely affected by current or future hostilities involving Israel or a significant recession or downturn in the economic or financial condition of Israel.

Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. A state of hostility, varying in degree and intensity, has led to security and economic problems for Israel in recent years. Tensions in the region increased significantly during the third quarter of fiscal 2009 between Israel and Hamas in the Gaza strip. These hostilities can adversely affect Israel s relationship with a number of countries in the region and elsewhere, as well as its relationship with international organizations.

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While none of the Company s facilities in Israel have been directly affected by hostile operations, there can be no assurance that a further escalation of hostilities will not impact the Company s facilities. Furthermore, the Company s employees in Israel include members of the Israeli military reserves, some of whom have been called up for active duty. If a significant number of the Company s employees in Israel are called up for active duty in the military, the Company s operations in Israel may be materially adversely affected.

Escalations of hostilities have disruptive effects on Israel s economy, and any international economic sanctions against Israel could further harm Israel s economy. These economic developments could have an adverse effect on the Company s Israel Consumer Products and Israel Pharmaceutical and Diagnostic Products businesses.

Furthermore, certain parties with whom the Company does business may decline to travel to Israel, which would force the Company to make alternative arrangements where necessary. The United States Department of State has at times issued an advisory regarding travel to various sections of Israel. As a result of the State Department s advisories, the FDA has at various times curtailed or prohibited its inspectors from traveling to Israel to inspect the facilities of Israeli companies, and should this occur with respect to the Company s Israeli facilities, the FDA could withhold approval for new products intended to be produced at those facilities.

Although it has not yet occurred, the political and security situation in Israel may result in certain parties with whom the Company has contracts claiming that they are not obligated to perform their commitments pursuant to force majeure provisions of those contracts.

The Company could experience disruption of its manufacturing and research and development facilities due to terrorist acts or military actions. If terrorist acts or military actions were to result in substantial damage to the Company s facilities, business activities would be disrupted since, with respect to most products, the Company would need to obtain prior FDA approval for a change in manufacturing site. The Company s insurance may not adequately compensate it for losses that may occur and any losses or damages incurred by the Company could have a material adverse effect on its business.

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

Financial and Credit Liquidity Crisis

The financial and credit liquidity crisis could have a negative impact on the Company s business. Although the Company s lenders have made commitments to make funds available to it in a timely fashion, if the current financial and credit liquidity crisis worsens (or new information becomes publicly available impacting the institutions credit rating or capital ratios), its lenders may be unable or unwilling to lend money pursuant to the Company s existing credit facilities. In addition, if the Company determines that it is appropriate or necessary to raise capital in the future, the cost of raising funds through the debt or equity markets may be more expensive or those markets may be unavailable. If the Company is unable to use its existing credit facilities or raise funds through debt or equity markets, it could materially and adversely affect the Company s liquidity or ability to follow its key growth strategies.

The Company s customers and suppliers may be adversely affected by the financial and credit liquidity crisis. Although the Company actively reviews the credit worthiness of its customers and suppliers, it cannot fully predict to what extent they may be negatively impacted and thus to what extent its own operations would be disrupted.

The Company invests cash and cash equivalents primarily in demand deposits and other short-term instruments with maturities of three months or less at the date of purchase. Since the advent of the global financial crisis in the first calendar quarter of 2008, the Company has maintained a balance between objectives of safety of principal, liquidity and return by investing primarily in U.S., federal, state and local government obligations, direct obligations of local sovereign

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governments and in bank obligations of the Company s credit banks meeting a minimum third party credit rating standard. The value of the Company s assets, including securities held for investment, may be adversely affected by the financial and liquidity crisis.

Further declines in global financial markets could contribute to a reduction of the Company s stock price, liquidity and overall financial condition.

Business Acquisitions and Divestitures

The Company s failure to successfully integrate acquisitions could have a negative effect on its operations. In addition, the lack of performance of acquisitions could cause financial difficulties.

As part of the Company s strategy, it evaluates potential acquisitions in the ordinary course of business, some of which could be and have been material. Acquisitions involve a number of risks and present financial, managerial and operational challenges. Integration activities may place substantial demands on the Company s management, operational resources and financial and internal control systems. Customer dissatisfaction or performance problems with an acquired business, technology, service or product could also have a material adverse effect on the Company s reputation and business.

The Company also evaluates the performance of all business units against a return on invested capital (ROIC) threshold. Underperforming assets typically have a specific period to improve performance before other strategic alternatives are considered. The Company s inability to successfully divest or sell assets in a timely manner could have a negative effect on its operations. In addition, the process of divestitures could cause strains on the ongoing operations of the Company.

Patent and Trade Dress Issues

The Company s ability to bring new products to market is limited by certain patent, trademark and trade dress factors including, but not limited to, the existence of patents protecting brand products for the Consumer Healthcare, Rx Pharmaceuticals and API segments and the regulatory exclusivity periods awarded on products that have switched from Rx to OTC status. The cost and time to develop these prescription and switch products is significantly greater than the rest of the new products that the Company seeks to introduce. Moreover, the manufacture, use and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. The Company may have to defend against charges that it violated patents or proprietary rights of third parties. The Company s defense against charges that it infringed third party patents or proprietary rights could require the Company to incur substantial expense and to divert significant effort of its technical and management personnel. If the Company is found to have infringed on the rights of others, it could lose its right to develop or manufacture some products or could be required to pay monetary damages or royalties to license proprietary rights from third parties.

Although the parties to patent and intellectual property disputes in the pharmaceutical industry have often settled their disputes through licensing or similar arrangements, the costs associated with these arrangements may be substantial and could include ongoing royalties. Furthermore, the Company cannot be certain that the necessary licenses would be available to it on terms it believes to be acceptable. As a result, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent the Company from manufacturing and selling a number of its products.

At times, the Company may seek approval to market ANDA products before the expiration of patents for those products, based upon its belief that such patents are invalid, unenforceable or would not be infringed by its products. As a result, the Company may face significant patent litigation. Depending upon a complex analysis of a variety of legal and commercial factors, the Company may, in certain circumstances, elect to market a generic pharmaceutical product while litigation is pending, before any court decision or while an appeal of a lower court decision is pending. This is referred to in the pharmaceutical industry as an at risk launch. The risk involved in an at risk launch can be substantial because, if a patent holder ultimately prevails, the remedies available to such holder may include, among other things, damages measured by the profits lost by the holder, which are often significantly higher than the profits the Company makes from

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selling the generic version of the product. By electing to proceed in this manner, the Company could face substantial damages if the final court decision is adverse to the Company. In the case where a patent holder is able to prove that the Company s infringement was willful or exceptional , the definition of which is subjective, the patent holder may be awarded up to three times the amount of its actual damages. Though the Company has participated in an at risk launch in the past, it is currently not marketing any products subject to an at risk launch.

Israel Government Grants and Tax Benefits

The Company has received grants for research and development from the Office of the Chief Scientist in Israel s Ministry of Industry and Trade. To continue to be eligible for these grants, the Company s development projects must be approved by the Chief Scientist on a case-by-case basis. If the Company s development projects are not approved by the Chief Scientist, the Company will not receive grants to fund these projects, which would increase research and development costs. The receipt of such grants subjects the Company to certain restrictions and pre-approval requirements which may be conditioned by additional royalty payments with rights to transfer intellectual property and/or production abroad. The Company also receives tax benefits, in particular exemptions and reductions, as a result of the approved enterprise status of certain existing operations in Israel. To be eligible for these tax benefits, the Company must maintain its approved enterprise status by meeting conditions, including making specified investments in fixed assets located in Israel and investing additional equity in itself and its Israeli subsidiaries and by meeting projections provided to the regulatory agencies. If the Company fails to meet these conditions in the future, the tax benefits would be canceled, and the Company could be required to refund the tax benefits already received. These tax benefits may not be continued in the future at their current levels or at any level. If such benefits are reduced or eliminated in the future, the Company s results of operations will be adversely impacted.

Manufacturing Facilities

The Company s U.S. operations are concentrated in Michigan, South Carolina, New York and Florida. Approximately 78% of the Company s revenues are related to these manufacturing facilities. The Company has concentrated manufacturing facilities in Israel, which comprise approximately 8% of the Company s revenues. A significant disruption resulting from, but not limited to, fire, tornado, storm, cyber attacks, material supply, insufficient quality, or pandemic at any of the Company s facilities could impair its ability to develop, produce and/or ship products on a timely basis, which could have a material adverse effect on the Company s business, financial position and operating results.

Protection of Intellectual Property Rights

The Company s success with certain of its products depends, in part, on its ability to protect and defend its intellectual property rights. If the Company fails to adequately protect its intellectual property, competitors may manufacture and market similar products. The Company has been issued patents covering certain of its products, and has filed, and expects to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the U.S. Any existing or future patents issued to or licensed by the Company may not provide it with any significant competitive advantages for its products or may even be challenged, invalidated or circumvented by competitors. In addition, such patent rights may not prevent the Company s competitors from developing, using or commercializing non-infringing products that are similar or functionally equivalent to its products.

The Company also relies on trade secrets, unpatented proprietary know-how and continuing technological innovation that it seeks to protect, in part by confidentiality agreements with licensees, suppliers, employees and consultants. If these agreements are breached, the Company may not have adequate remedies for any such breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, trade secrets and proprietary technology may otherwise become known or be independently developed by competitors or, if patents are not issued with respect to products arising from research, the Company may not be able to maintain the value of such intellectual property rights.

Customs and Trade Regulation

The Company imports and exports products and raw materials from several jurisdictions around the world. This process involves Company subsidiaries and third parties operating in a number of jurisdictions with different customs and import/

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export regulations. The regulations are subject to change from time to time and the Company cannot predict the nature, scope or impact of these changes upon the Company s operations. The Company is subject to periodic reviews and audits by U.S. and foreign authorities responsible for administering these regulations. To the extent that the Company is unable to successfully defend itself against an audit or review, the Company may be required to pay assessments and penalties and increased duties, which may, individually or in the aggregate, negatively impact the Company s gross margins and operating results. Certain of the Company s facilities operate in a special purpose subzone established by the U.S. Department of Commerce Foreign Trade Zone Board, which allows the Company certain tax advantages on products and raw materials shipped through these facilities. If the U.S. Department of Commerce Foreign Trade Zone Board were to revoke the subzone designation or limit its use by the Company, the Company could be subject to increased duties, which may negatively impact the Company s gross margins and operating results.

International Operations

The Company sources certain key raw materials from foreign suppliers in countries that include, but are not limited to, Canada, China, Denmark, Germany, India and Mexico. The Company continues to increase its revenues outside the U.S. The Company s primary markets for the sale of its products outside the U.S. are Canada, Germany, Israel, Mexico and the U.K. The Company may have difficulty in international markets due, for example, to regulatory barriers, the necessity of adapting to new regulatory systems and problems related to markets with different cultural bases and political systems. Sales to customers outside the U.S. and foreign raw material purchases expose the Company to a number of risks, including unexpected changes in regulatory requirements, possible difficulties in enforcing agreements, longer payment cycles, longer shipping lead-times, inefficient port operations, exchange rate fluctuations, difficulties obtaining export or import licenses, the imposition of withholding or other taxes, economic or political instability, embargoes, military hostilities or exchange controls. Should any of these risks occur, they may have a material adverse impact on the operating results of the Company.

Dependence on Personnel

The Company s future success will depend in large part upon its ability to attract and retain highly skilled employees. Key functions for the Company include executive managers, operational managers, research and development scientists, information technology specialists, financial and legal specialists, regulatory professionals, quality compliance specialists and sales/marketing personnel. Should the Company be unable to attract or retain key qualified employees, future operating results may be adversely impacted.

Goodwill and Other Intangibles

The Company tests goodwill for impairment annually or more frequently if changes in circumstances or the occurrence of events suggest impairment exists. The test for impairment requires the Company to make several estimates about fair value, most of which are based on projected future cash flows. Changes in these estimates may result in the recognition of an impairment loss. The Company s testing in the 2009 fiscal year resulted in no impairment charges related to goodwill.

Other intangible assets consist of a portfolio of individual developed product technology/formulation and product rights, distribution and license agreements, customer relationships and trade names and trademarks. For intangible assets subject to amortization, an impairment analysis is performed whenever events or changes in circumstances indicate that the carrying amount of any individual asset may not be recoverable. An impairment loss is recognized if the carrying amount of the asset is not recoverable and its carrying amount exceeds its fair value. Any significant change in market conditions, estimates or judgments used to determine expected future cash flows that indicate a reduction in carrying value may give rise to impairment in the period that the change becomes known. See Note 8 for further information regarding impairment of intangible assets.

Insurance Costs

The Company maintains insurance, including property, general and product liability, and directors and officers liability, to protect itself against potential loss exposures. To the extent that losses occur, there could be an adverse effect on the

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Company s financial results depending on the nature of the loss and the level of insurance coverage maintained by the Company. The Company cannot predict whether deductible or retention amounts will increase or whether coverage will be reduced in the future. From time to time, the Company may reevaluate and change the types and levels of insurance coverage that it purchases.

Exposure to Product Liability Claims

The Company, like retailers and other distributors and manufacturers of products that are ingested, is exposed to product liability claims in the event that, among other things, the use of its products results in injury. There is no assurance that product liability insurance will continue to be available to the Company at an economically reasonable cost (or at all for certain products) or that the Company s insurance will be adequate to cover liability that the Company incurs in connection with product liability claims. See Item 3. Legal Proceedings.

Capital Requirements and Liquidity

The Company maintains a broad product line to function as a primary supplier for its customers. Capital investments are driven by growth, technological advancements, cost improvement and the need for manufacturing flexibility. Estimation of future capital expenditures could vary materially due to the uncertainty of these factors. If the Company fails to stay current with the latest manufacturing and packaging technology, it may be unable to competitively support the launch of new product introductions.

The Company anticipates that cash, cash equivalents, investment securities, cash flows from operations and borrowings under its credit facilities will substantially fund working capital and capital expenditures. The Company has historically evaluated acquisition opportunities and anticipates that acquisition opportunities will continue to be identified and evaluated in the future. The historical growth of sales and profits has been significantly influenced by acquisitions. There is no assurance that future sales and profits will, or will not, be impacted by acquisition activities. The Company s current capital structure, results of operations and cash flow needs could be materially impacted by acquisitions.

The Company s senior credit facilities, the agreements governing its senior notes and agreements governing its other indebtedness contain a number of restrictions and covenants that limit the Company s ability to make distributions or other payments to its investors and creditors unless certain financial tests or other criteria are satisfied. The Company also must comply with certain specified financial ratios and tests. These restrictions could affect the Company s ability to operate its business and may limit its ability to take advantage of potential business opportunities, such as acquisitions. If the Company does not comply with the covenants and restrictions contained in its senior credit facilities, agreements governing its senior notes and agreements governing its other indebtedness, the Company could be in default under those agreements, and the debt, together with accrued interest, could then be declared immediately due and payable. Any default under the Company s senior credit facilities or agreements governing its senior notes or other indebtedness could lead to an acceleration of debt under other debt instruments that contain cross-acceleration or cross-default provisions. If the Company s indebtedness is accelerated, there can be no assurance that it would be able to repay or refinance its debt or obtain sufficient new financing.

The Company has various maturity dates associated with it credit facilities, senior notes and other debt facilities. There is no assurance that cash, future borrowings or equity financing will be available for the payment or refinancing of its indebtedness. Further, there is no assurance that future refinancings or renegotiations of the Company s senior credit facilities, senior notes or other debt facilities, or additional agreements will not have materially different or more stringent terms.

Item 1B. Unresolved Staff Comments.

Not applicable.

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Item 2. Properties.

The following is a list of the primary facilities owned or leased by the Company and the segment(s) that are generally supported by the facility as of August 10, 2009:

Location	No. of Facilities	Approx. Square Footage Owned	Approx. Square Footage Leased	Segments
Michigan	24	2,000,000	460,000	Consumer Healthcare, Rx Pharmaceuticals
New York	3	-	267,000	Consumer Healthcare, Rx Pharmaceuticals
South Carolina	3	200,000	260,000	Consumer Healthcare
Florida	2	-	118,000	Consumer Healthcare
Barnsley, U.K.	1	-	100,000	Consumer Healthcare
Braunton, U.K.	1	230,000	-	Consumer Healthcare
Ramos Arizpe, Mexico	3	170,000	30,000	Consumer Healthcare
Guadalajara Jalisco, Mexico	1	27,000	-	Consumer Healthcare
Yeruham, Israel[2]	2	1,003,000	-	Rx Pharmaceuticals, Israel Pharmaceuticals and Diagnostic Products[1], API, Israel Consumer Products
B nei-Brak, Israel[2]	4	-	125,000	Rx Pharmaceuticals, Israel Pharmaceuticals and Diagnostic Products[1], API, Israel Consumer Products
Ramat Hovav, Israel	1	437,000	-	API
Petach-Tikva, Israel	1	216,000	-	Israel Consumer Products
Wiesbaden, Germany	1	-	114,000	API

(1) Represents operating segment in Other category.
(2) Amounts include Israel Consumer Products operating segment, which is reported as discontinued operations.

All of the facilities above provide manufacturing, logistics and offices to support the respective segment and/or location. The Company leases other minor properties for logistics and offices in the U.S., Israel, Mexico, India and China. The Company considers all of its properties to be well-maintained and suitable for the intended purpose of the facility.

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Item 3. Legal Proceedings. (Dollar amounts in thousands)

On March 11, 2009, a purported shareholder of the Company named Michael L. Warner filed a lawsuit in the United States District Court for the Southern District of New York against the Company and certain of its officers and directors, including Joseph Papa and Judy Brown, among others. The plaintiff sought to represent a class of purchasers of the Company s common stock during the period between November 6, 2008 and February 2, 2009. The complaint alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the Exchange Act). The plaintiff generally alleged that the Company misled investors by failing to disclose, prior to February 3, 2009, that certain auction rate securities held by the Company, totaling approximately $18,000 in par value (the ARS), had been purchased from Lehman Brothers Holdings, Inc. (Lehman). The plaintiff asserted that omission of the identity of Lehman as the seller of the ARS was material because after Lehman s bankruptcy filing, on September 15, 2008, the Company allegedly became unable to look to Lehman to repurchase the ARS at a price near par value. The complaint sought unspecified damages and unspecified equitable or injunctive relief, along with costs and attorneys fees.

On June 15, 2009, the Court endorsed a stipulation appointing several purported shareholders of the Company, namely CLAL Finance Batucha Investment Management, Ltd., The Phoenix Insurance Company, Ltd., Excellence Nessuah Mutual Funds Management, Ltd. and Excellence Nessuah Gemel & Pension, Ltd., as Co-Lead Plaintiffs. On July 31, 2009, these Co-Lead Plaintiffs filed an amended complaint. The amended complaint dropped all claims against the individual defendants other than Joseph Papa and Judy Brown, and added a control person claim under Section 20(a) of the Exchange Act against the members of the Company s Audit Committee, namely Laurie Brlas, Gary Kunkle and Ben-Zion Zilberfarb. The amended complaint asserts the same statutory claims and contains the same class action allegations as the original pleading. The amended complaint alleges that the Company should have disclosed, prior to February 3, 2009, that Lehman had sold the ARS to the Company and had provided the allegedly inflated valuation of the ARS that the Company adopted in its Form 10-Q filing for the first quarter of fiscal 2009, which was filed with the SEC on November 6, 2008. Under a Scheduling Order, the Company has until September 14, 2009 to respond to the amended complaint. The Company believes that the law suit is without merit and intends to defend the case vigorously.

On or about June 2, 2009, a purported shareholder of the Company named Bill Drinkwine filed a purported shareholder derivative complaint in the Circuit Court of Allegan County, Michigan against a number of officers and directors of the Company, including those officers and directors named as defendants in the federal securities suit described above. Like the federal securities suit, the state court complaint alleges that the Company misled investors by failing to disclose, prior to February 3, 2009, that the ARS had been purchased from Lehman and allegedly became worthless when Lehman filed for bankruptcy. The complaint asserts that the officer and director defendants violated their fiduciary duties to the Company by selling shares of their personally-held Perrigo stock during the five-month period between Lehman s bankruptcy filing and the Company s February 3, 2009 disclosure of the write-down of the value of the ARS. The complaint seeks to recover for Perrigo the proceeds received by the officer and director defendants from such stock sales.

Prior to filing the suit, on March 3, 2009, Mr. Drinkwine made a demand on the Company s Board of Directors that Perrigo bring the suit directly against the accused officers and directors. In response to that demand, the Perrigo Board appointed a committee of all independent, disinterested directors to investigate Mr. Drinkwine s allegations. The committee retained independent counsel to assist it in that investigation. The committee and its counsel conducted an extensive investigation and concluded that Mr. Drinkwine s allegations are entirely without merit and, consequently, that it would not be in Perrigo s best interests for the suit to go forward. Based on the findings of that investigation, the Company plans to seek dismissal of the complaint pursuant to Section 495 of the Michigan Business Corporation Act, which provides that when a committee of all independent, disinterested directors makes a good faith determination, based upon a reasonable investigation, that the maintenance of a derivative suit would not be in the best interests of the corporation, the court shall dismiss the derivative proceeding.

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

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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 $74,800. 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.

In addition to the foregoing discussion, the Company has pending certain other legal actions and claims incurred in the normal course of business. The Company believes that it has meritorious defenses to these lawsuits and/or is covered by insurance and is actively pursuing the defense thereof. The Company believes the resolution of all of these matters will not have a material adverse effect on its financial condition and results of operations as reported in the accompanying consolidated financial statements. However, depending on the amount and timing of an unfavorable resolution of these lawsuits, the Company s future results of operations or cash flow could be materially impacted in a particular period.

Item 4. Submission of Matters to a Vote of Security Holders.

No matter was submitted to the vote of security holders during the fourth quarter of fiscal 2009.

Additional Item. Executive Officers of the Registrant.

The executive officers of the Company and their ages and positions as of August 10, 2009 were:

Name	Age	Position
Judy L. Brown		