PERRIGO Co plc
Form 10-KT
February 25, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
[ ] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended
or
[X] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from June 28, 2015 to December 31, 2015
Commission file number 001-36353
Perrigo Company plc
(Exact name of registrant as specified in its charter)

Ireland	N/A
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland	-
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: +353 1 7094000
Securities registered pursuant to Section 12(b) of the Act:

Ordinary shares, €0.001 par value	New York Stock Exchange
Title of each class	Name of each exchange on which registered

Securities registered pursuant to Section 12(g) of the Act:
None
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.	YES [X] NO [ ]
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 of Section 15(d) of the Act.	YES [ ] NO [X]
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.	YES [X] NO [ ]
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).	YES [X] NO [ ]
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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-KT or any amendment to this Form 10-KT.	[ ]

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	[ ]

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of our ordinary shares on December 31, 2015 as reported on the New York Stock Exchange, was $20,712,935,064. Ordinary shares 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 February 19, 2016, the registrant had 143,198,631 outstanding ordinary shares.

Documents incorporated by reference:

The information called for by Part III will be incorporated by reference from the Registrant's definitive Proxy Statement for its Annual Meeting of Shareholders to be filed pursuant to Regulation 14A or will be included in an amendment to this Form 10-KT.

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FORM 10-KT
SIX MONTHS ENDED DECEMBER 31, 2015
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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 our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our, or our industry's, actual results, levels of activity, performance or achievements to be materially different from those expressed or implied by any forward-looking statements. In particular, statements about our expectations, beliefs, plans, objectives, assumptions, future events or future performance contained in this report, including certain statements contained in “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,” “potential” or the negative of those terms or other comparable terminology.

We have based these forward-looking statements on our current expectations, assumptions, estimates and projections. While we believe 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 our control. Risks and uncertainties include risks related to the timing, amount and cost of share repurchases, the successful integration of the Omega Pharma Invest N.V. business, and the ability to execute and achieve the desired benefits of announced acquisitions, divestitures, and initiatives. These and other important factors, including those discussed in this report under "Risk Factors" and in any subsequent filings with the Securities and Exchange Commission, 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, we disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

TRADEMARKS, TRADENAMES AND SERVICE MARKS

This report contains trademarks, trade names and service marks that are the property of Perrigo Company plc, as well as, for informational purposes, trademarks, trade names, and service marks that are the property of other organizations. Solely for convenience, certain trademarks and trade names referred to in this report appear without the ®, ™ and SM symbols, but those references are not intended to indicate that we or the applicable owner, as the case may be, will not assert, to the fullest extent under applicable law, our or their rights to such trademarks, trade names, and service marks.

PERIOD PRESENTED

References herein to the six months ended December 31, 2015 represent the transition period from June 28, 2015 to December 31, 2015. References herein to the six month period ended December 27, 2014 represent the comparative prior year period from June 29, 2014 to December 27, 2014.

Perrigo Company plc - Item 1
Business Overview

PART I.

ITEM 1. BUSINESS

Perrigo Company plc was incorporated under the laws of Ireland on June 28, 2013. We became the successor registrant to Perrigo Company, a Michigan corporation, on December 18, 2013 in connection with the acquisition of Elan Corporation, plc ("Elan"), which is discussed further in Item 8. Note 2. Unless the context requires otherwise, the terms "Perrigo", the "Company", "we," "our," "us," and similar pronouns used herein refer to Perrigo Company plc, its subsidiaries, and all predecessors of Perrigo Company plc and its subsidiaries.

WHO WE ARE

We are a leading global over-the-counter ("OTC") consumer goods and specialty pharmaceutical company, offering patients and customers high quality products at affordable prices. From our beginning in 1887 as a packager of home remedies, we have grown to become the world's largest manufacturer of OTC healthcare products and supplier of infant formulas for the store brand market. We are also a leading provider of generic extended topical prescription products, and we receive royalties from sales of the multiple sclerosis drug, Tysabri®. We provide “Quality Affordable Healthcare Products®” across a wide variety of product categories and geographies, primarily in North America, Europe, and Australia, as well as in other markets, including Israel and China.

TRANSITION PERIOD

Our fiscal year previously consisted of a 52- or 53-week year ending on or around June 30 of each year with each quarter ending on the Saturday closest to each calendar quarter end. Beginning on January 1, 2016, we are changing our fiscal year to begin on January 1 and end on December 31 of each year. This transition report on Form 10-KT discloses the results of our operations for the transition period from June 28, 2015 to December 31, 2015, which is referred to in this report as the six months ended December 31, 2015. The comparative prior year period is June 29, 2014 through December 27, 2014, and is referred to within this report as the six months ended December 27, 2014. Going forward, we will continue to cut off our quarterly accounting periods on the Saturday closest to the end of the calendar quarter, with the fourth quarter ending on December 31 of each year.

Perrigo Company plc - Item 1
Business Overview

MAJOR DEVELOPMENTS IN OUR BUSINESS

Rejection of Mylan Unsolicited Tender Offer

In April 2015, Mylan N.V. ("Mylan") made a series of proposals to acquire a controlling interest in our outstanding ordinary shares (the “Proposals”). Our Board of Directors unanimously rejected each of the Proposals, concluding that they substantially undervalued the Company and our future growth prospects and were not in the best interests of our shareholders. On September 14, 2015, Mylan commenced an unsolicited tender offer to purchase our outstanding ordinary shares (the "Tender Offer"). The Tender Offer period concluded on November 13, 2015, with Mylan failing to receive greater than 50% of the outstanding Perrigo ordinary shares, and the Tender Offer was terminated. During the six months ended December 31, 2015, the total cost to effectively defend against Mylan was $86.9 million, which was recorded in Administration expense.

Organizational Improvements

On October 22, 2015, we announced our intention to undertake certain initiatives designed to increase operational efficiency and improve our return on invested capital by globalizing our supply chain through global shared service arrangements, streamlining our organizational structure, and disposing of certain assets.

Omega Acquisition

On March 30, 2015, we acquired Omega Pharma Invest N.V. ("Omega"), for $3.0 billion in equity and cash and assumed debt of $1.4 billion, for a total purchase price of $4.4 billion. Prior to its acquisition, Omega was one of the largest OTC companies in Europe. The Omega acquisition expanded our OTC leadership position into continental Europe, accelerated our international expansion and geographic diversification through enhanced scale and a broader footprint, and diversified our revenue and cash flow streams.

We have already begun utilizing the broader European platform established through the Omega acquisition, acquiring a portfolio of well-established OTC brands primarily in Europe from GlaxoSmithKline Consumer Healthcare (“GSK”), and acquiring Naturwohl Pharma, GmbH ("Naturwohl"), with its leading German dietary supplement brand, Yokebe®. Additional information on the Omega, GSK, and Naturwohl acquisitions can be found in Item 8. Note 2.

Elan Acquisition

On December 18, 2013, we acquired Elan in a cash and stock transaction totaling $9.5 billion. The acquisition led to the creation of our new corporate structure headquartered in Dublin, Ireland. We have utilized this structure to continue to grow in our core markets and to further expand outside of the U.S. The acquisition also provided us with our Tysabri® royalty stream, enhancing our operating cash flows and further diversifying our net sales. Additional information on the Elan acquisition can be found in Item 8. Note 2.

OUR SEGMENTS

Our reporting segments are as follows:

- Consumer Healthcare ("CHC") is focused primarily on the global sale of OTC store brand products including cough, cold, allergy and sinus, analgesic, gastrointestinal, smoking cessation, infant formula and food, Vitamins, Minerals and Supplements ("VMS"), animal health, and diagnostic products.

- Branded Consumer Healthcare ("BCH") develops, manufactures, markets, and distributes many well-known European OTC brands in the natural health and VMS, cough, cold and allergy, smoking cessation, personal care and derma-therapeutics, lifestyle, and anti-parasite categories.

- Prescription Pharmaceuticals ("Rx") develops, manufactures, and markets a portfolio of generic and specialty pharmaceutical prescription drugs primarily for the U.S. and United Kingdom ("U.K.") markets.

Perrigo Company plc - Item 1
Business Overview

- Specialty Sciences is comprised primarily of royalties received from assets focused on the management of multiple sclerosis (Tysabri®).

We also have an "Other" segment comprised of our active pharmaceutical ingredients ("API") business, which develops, manufactures, and markets API used worldwide by both generic and branded pharmaceutical companies. Financial information related to our business segments and geographic locations can be found in Item 8. Note 19.

NEW PRODUCTS

We consider a product to be new if it was reformulated or a product line extension due to changes in strength, flavor, color, etc.; a change in product status from "prescription only" ("Rx") to OTC; a new generic or branded launch; a new dosage form; 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. New product sales totaled $231.1 million and $77.3 million for the six months ended December 31, 2015 and December 27, 2014, respectively, and $273.8 million, $231.4 million, and $122.3 million for the fiscal years ended June 27, 2015, June 28, 2014, and June 29, 2013, respectively.

CONSUMER HEALTHCARE

Overview

The CHC segment is focused primarily on the global sale of OTC store brand products, including cough, cold, allergy and sinus, analgesic, gastrointestinal, smoking cessation, infant formula and food, VMS, animal health, and diagnostic products. We are a market leader in many geographies, including the U.S., U.K., and Mexico, and we are growing our position in Australia. We are a global leader of consumer healthcare products sold to consumers via store brands or our own label brands. Consumer awareness and knowledge of the quality and value that OTC store brand products represent continues to grow due to retailer efforts to promote their own label programs. During the six months ended December 31, 2015, our CHC segment represented approximately 50% of consolidated net sales.

The CHC segment develops, manufactures, and markets products that are comparable in quality and effectiveness to national brands. Store brand products must meet the same U.S. Food and Drug Administration ("FDA") requirements as national brands within the U.S., and the requirements of comparable regulatory bodies outside the U.S. In most instances, our product packaging is designed to attract consumers and to invite and reinforce comparison to national brand products, while communicating store brand value to consumers.

The cost of store brand products to retailers is significantly lower than that of comparable nationally advertised brand-name products. Generally, retailers’ dollar profit per unit of store brand product is greater than the dollar profit per unit of the comparable national brand product. The retailer, therefore, can price a store brand product below the competing national brand product and realize a greater profit margin. The consumer benefits by receiving a high quality product at a price below the comparable national brand product. As a result, our business model results in consumers saving money on their healthcare spending.

We are dedicated to being the leader in developing and marketing new OTC store brand products and have a research and development ("R&D") staff that we believe is one of the most experienced in the industry at developing products comparable in formulation and quality to national brand products. Our R&D team also responds to changes in existing national brand products by reformulating existing products. For example, in the OTC pharmaceutical market, certain new products are the result of changes in product status from Rx to OTC. These “Rx-to-OTC switches” require FDA

approval through a process initiated by the drug innovator. The drug innovator usually begins the process by filing a New Drug Application ("NDA"), which is often followed by filing an Abbreviated New Drug Application ("ANDA"). See "Government Regulation and Pricing" below for more information on these FDA processes.

New drugs are also marketed through the FDA's OTC monograph process, which allows for the production of drugs that are generally recognized as safe and effective without pre-market approval. The CHC segment also develops, manufactures, and distributes certain branded products when the strategy is synergistic with our store

Perrigo Company plc - Item 1
CHC

brand business. Branded products include the Good Sense®, Sergeant's®, Sentry®, Herron®, and PetArmor® value brands, and the ScarAway® brand name.

We manufacture our products at our plants in the U.S., U.K., Mexico, Israel, and Australia, and we source our remaining needs from third parties. We rely on both internal R&D and strategic product development agreements with outside sources to develop new products. In addition, in order to maximize both our capacity and sales of proprietary formulas, we engage in contract manufacturing, which involves producing unique ANDAs and monograph products through partnerships with major pharmaceutical and direct-to-consumer companies.

We believe that our CHC segment's future growth will be driven by global population growth and an aging population with fewer people to fund healthcare within the developed world, which will increase the need for the greater value that our store brands products provide consumers. In addition, we believe that new products and more products switching from Rx to OTC (as described above) will continue to drive growth within the segment.

Recent Developments

As part of our announced organizational improvements, we are pursuing the sale of our VMS business within the CHC segment and expect the sale to take place during the first half of 2016. As of December 31, 2015, we reclassified the related VMS net assets to "held for sale" as discussed in Item 8. Note 9.

On August 28, 2015, we acquired ScarAway®, a leading U.S. OTC scar management brand portfolio comprised of five products, from Enaltus, LLC for $26.7 million in cash. This acquisition serves as our entry into the branded OTC business in the U.S. We may pursue additional branded OTC opportunities in the U.S. market.

Products

Our CHC segment offers products in the following categories:

Product Category	Description
Analgesics	Pain relievers and fever reducers
Cough/cold/allergy/sinus	Cough, cold, allergy, and sinus products
Gastrointestinal	Antacids, anti-diarrheal, and anti-heartburn products
Infant nutritionals	Infant formula and food products
Smoking cessation	Gums, lozenges, and other products designed to help users quit smoking
Animal health	Pet health and wellness products
VMS	Vitamins, minerals, and dietary supplements
Other	Feminine hygiene, diabetes care, dermatological care, diagnostic products, scar management, and other miscellaneous healthcare products

Perrigo Company plc - Item 1
CHC

The chart below reflects net sales by product category in the CHC segment for the six months ended December 31, 2015.

We launched a number of new CHC products in the six months ended December 31, 2015, most notably a line of reformulated infant formula products. Net sales related to new CHC products totaled $125.3 million and $36.3 million for the six months ended December 31, 2015 and December 27, 2014, respectively, and $155.2 million, $83.4 million, and $71.6 million for the fiscal years ended June 27, 2015, June 28, 2014, and June 29, 2013, respectively.

We, on our own or in conjunction with partners, received final approval from global health authorities for 38 new products within the CHC segment in the six months ended December 31, 2015, and as of December 31, 2015, we had 148 new product applications pending approval.

Sales and Marketing

Our customers include major global, national, and regional retail drug, supermarket, and mass merchandise chains such as Walmart, CVS, Walgreens/Rite Aid, Kroger, Target, Dollar General, Sam’s Club, Costco, Petco, Petsmart, Boots (U.K.), Tesco (U.K.), ASDA (U.K.), Woolworth (Australia), Coles (Australia), and major wholesalers, including McKesson, Cardinal Health, and AmerisourceBergen.

We seek 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 CHC segment employs its own sales force to service larger customers, and it uses industry brokers for other retailers. Field sales employees, with support from marketing and customer service, are assigned to specific customers in order to work most effectively with the customer. They assist customers by developing customized brand management and in-store marketing programs for customers' store brand products.

The primary objective of this store brand management approach is to enable our customers, retailers and wholesalers, to increase sales of their own store brand products by communicating store brand quality and value to the consumer and by inviting comparison to national brand products. Our sales and marketing personnel assist customers in the development and introduction of new store brand products and in the promotion of customers’ existing store brand products by providing market information; establishing individualized promotions and marketing programs, which may include floor displays, bonus sizes, coupons, rebates, store signs, and promotional packs; and performing consumer research.

Perrigo Company plc - Item 1
CHC

In contrast with national brand manufacturers, which incur considerable advertising and marketing expenditures targeted directly to the end user or consumer, the CHC segment's primary marketing efforts are channeled through retailers and wholesalers and reach the consumer through our customers' in-store marketing programs and our digital media programs. Because the retail profit margin for store brand products is generally higher than for national brand products, retailers and wholesalers often commit funds for additional promotions.

Our animal health category, which has a greater emphasis on value-branded products, promotes product awareness through direct-to-consumer advertising including television commercials, on-line advertising, in-store display vehicles, and social media. In addition to in-store marketing programs, our infant formula category markets directly to consumers and healthcare professionals.

Competition

The markets for OTC pharmaceuticals, nutritional products, and infant formula are highly competitive. Our primary competitors include manufacturers, such as LNK International, Inc., PL Developments, International Vitamin Corporation, and Dr. Reddy's Labs, and brand-name pharmaceutical and consumer product companies such as Johnson & Johnson, Pfizer, Bayer AG, Nestle S.A. (Gerber), Abbott Nutrition, NBTY, and Mead Johnson Nutrition Co. The competition is highly fragmented in terms of geographic market coverage and product categories, such that a competitor generally does not compete across all product lines. However, some competitors do have larger sales volumes in certain of our categories. Additionally, national brand companies tend to have more resources committed to marketing their products and could in the future manufacture store brands of their products at lower prices than their national brand products. Competition is based on a variety of factors, including price, quality, assortment of products, customer service, marketing support, and approvals for new products. See Item 1A. Risk Factors - Risks Related to Operations for additional information and risks associated with competition.

BRANDED CONSUMER HEALTHCARE

Overview

We established the BCH segment during the fourth quarter of the fiscal year ended June 27, 2015, and it is comprised primarily of branded OTC sales attributable to Omega. The BCH segment develops, manufactures, markets, and distributes many well-known European OTC brands in the natural health and VMS, cough, cold and allergy, personal care and derma-therapeutics, lifestyle, smoking cessation, and anti-parasite categories. In addition, the segment leverages its broad regulatory, sales, and distribution infrastructure to in-license and sell non-owned brands and generic pharmaceutical products. The BCH segment distributes these products through an extensive network of pharmacies in 36 countries, primarily in Europe. Many BCH products are top sellers in the markets in which they compete. During the six months ended December 31, 2015, the BCH segment represented approximately 23% of consolidated net sales.

Through continued investment in R&D and new technologies, the BCH segment strives to offer high quality products that meet consumers' needs. The combination of internal R&D, in-licensing, acquisitions, and partnerships support the product pipeline, both in terms of brand expansion and product improvement. Currently, most R&D is performed by external partners with oversight by our teams. The segment has seven plants dedicated to manufacturing certain of its products, but over 70% of its production is outsourced to third parties. We plan to bring some of the segment's R&D and manufacturing in-house as we integrate Omega into Perrigo operations.

Unlike the CHC segment, which develops and markets store brand products, the BCH segment focuses on building brands. In many markets outside of the U.S., a brand marketing strategy can be more effective than a store brand strategy due to the absence of mass merchandisers and pharmacy chains, and because consumer acceptance of store brands is not as developed as it is in the U.S. Additionally, the absence of a centralized regulatory environment within Europe adds to the complexity of obtaining approvals for products in these markets.

Perrigo Company plc - Item 1
BCH

While the BCH segment sells products from over 300 brands both on its own and through third parties, it focuses its resources on its "Top 20 brands", which are selected on the basis of their current sales and growth potential in the OTC market. Additional resources are allocated to these brands to build strong positions in the largest, most highly profitable categories in the OTC market, while maintaining leadership in smaller branded categories.

Recent Developments

On September 15, 2015, we completed our acquisition of Naturwohl, a Munich, Germany-based nutritional business known for its leading German dietary supplement brand, Yokebe®, for €133.5 million ($150.4 million) in cash. On August 28, 2015, we completed the acquisition of a portfolio of well-established OTC brands from GSK for €200.0 million ($223.4 million) in cash. The portfolio included smoking cessation products, cold and flu treatments, pain relief products, nasal decongestants, and cold sore management products sold primarily in Europe. Both acquisitions built upon the global platform we established through the Omega acquisition and expanded our market share in the European OTC market.

Products

Below are the categories in which the BCH segment competes and some of the top brands in each category.

Product Category	Description	Top 20 Brands
Natural Health and VMS	Vitamins, minerals, supplements, and various other natural remedies.	Biover®/Abtei® Davitamon®/Etixx® Granufink®/Bional® Bittner®/Aflubin®
Cough, Cold, and Allergy	Products that address respiratory symptoms, including traditional medications and alternative treatments such as aromatherapy and homeopathic solutions.	Bronchodual® Physiomer® Phytosun®/Valda® Prevalin®/Beconase® Solpadeine®/Antigrippine®
Personal Care and Derma-Therapeutics	Products for the face and body, including sun care, baby-specific, and feminine hygiene products, and solutions for various skin conditions and allergies such as eczema, psoriasis and rosacea.	ACO® Bodysol®/Galenco® Dermalex®(Repair) Lactacyd® Wartner®
Lifestyle	Weight management, pregnancy and fertility kits, pain relief, sleep management, smoking cessation, and eye care.	Paravet®/Clément-Thékan® Predictor® Silence®/Nytol® XLS (Medical)®
Anti-Parasite	Products focused on the elimination of parasites in both humans and pets including lice treatment and insect repellent.	Jungle Formula® Paranix®

Certain brands are considered "combination brands", as they are marketed under different names depending on the market in which they are sold. For these combination brands, we select the most appropriate products from each product line for the country where they will be marketed, then adopt the brand name that best matches local consumer

preference.

We launched a number of new BCH products in the six months ended December 31, 2015, most notably lifestyle products such as XLS Max strength and cough and cold products such as Bronchostop®. New product sales during the six months ended December 31, 2015 totaled $62.6 million. During 2016, the BCH segment will focus on re-invigorating growth behind the newly acquired GSK brands Niquitin® and Coldrex® and rolling out the Yokebe® meal replacement range across Europe. The BCH segment has more than 50 strategic new products in five product categories in development, with each of its Top 20 brands having a five-year innovation master plan.

Perrigo Company plc - Item 1
BCH

Sales and Marketing

Our customers include pharmacies, drug, and grocery stores located primarily in Europe, including Boots, ASDA, Tesco, DM, Rossmann, ETOS, and Kruidvat. The BCH segment sells its products through an established pharmacy sales force and an extensive network of pharmacists. Our sales representatives visit pharmacists daily, ensuring strong in-store visibility of our brands and facilitating pharmacist education programs. Our sales, marketing, and regulatory teams use training/merchandising teams to work in conjunction with base sales representatives to identify, implement, and defend healthcare claims for key products. We seek to attract key talent personnel from leading OTC, fast moving consumer goods ("FMCG"), and Rx companies to build strong local teams throughout the countries in which the BCH segment operates.

While BCH products have a higher average gross margin than products sold by the CHC segment, selling expenses are significantly higher for our BCH products due to the sales force mentioned above, as well as targeted advertising and promotional spending to enhance brand equity. Key marketing communication tools include TV commercials, consumer leaflets, product websites, and targeted promotional campaigns.

Competition

The competitive landscape of the European OTC market is highly fragmented, as local companies often hold leadership positions in individual product segments in particular countries. As a result, the relevant competition in each of the BCH segment's markets is mostly local, with Reckitt Benckiser, Boehringer Ingelheim, Novartis, and Johnson & Johnson as additional regional competitors. We believe our key advantage lies in our unique combination of best practices in sales, marketing, and product development from FMCG and OTC/Rx, while embracing the pharmacy channel to drive self-care. See Item 1A. Risk Factors - Risks Related to Operations for additional information and risks associated with competition.

PRESCRIPTION PHARMACEUTICALS

Overview

The Rx segment develops, manufactures, and markets a portfolio of generic and specialty pharmaceutical prescription drugs primarily for the U.S. and U.K. markets. We define this portfolio as predominantly "extended topical" and "specialty" as it encompasses a broad array of topical dosage forms such as creams, ointments, lotions, gels, shampoos, foams, suppositories, sprays, liquids, suspensions, solutions, and powders. The portfolio also includes select controlled substances, injectables, hormones, women's health products, oral solid dosage forms, and oral liquid formulations. During the six months ended December 31, 2015, the Rx segment represented approximately 20% of consolidated net sales.

Our current development areas include other delivery systems such as oral liquids, metered dose inhalers, injectables, and transdermal products, some of which we are developing with third parties. Our other areas of expertise include our production capabilities for controlled substance and hormonal products. In the U.S., R&D efforts focus on complex formulations, many of which require costly clinical endpoint trials. In the U.K., R&D focuses on oral liquid formulations for the branded Rx products for which liquid formulations are not available.

We manufacture our topical, specialty, and oral products in the U.S., Israel, and U.K., and also source from various FDA-approved third parties. Rx products are manufactured, labeled, and packaged in facilities that comply with strict regulatory standards and meet customers’ stringent requirements.

In addition, the Rx segment offers OTC products through the prescription channel (referred to as "ORx®", these products are marketed using the Perrigo name). ORx® products are OTC products that are available for pharmacy fulfillment and healthcare reimbursement when prescribed by a physician. We offer numerous ORx® products that are reimbursable through many health plans and the U.S. Medicaid and Medicare programs.

We actively collaborate with other pharmaceutical companies to develop, manufacture, and market certain products or groups of products. These types of agreements are common in the pharmaceutical industry. We may choose to enter into these types of agreements to, among other things, leverage our or our collaborators' scientific R&D expertise, or utilize our extensive marketing and distribution resources. See Item 8. Note 1 for more

Perrigo Company plc - Item 1
Rx Pharmaceuticals

information regarding our method for recognizing revenue and expenses related to collaboration agreements, as well as Item 8. Note 17 for more information regarding our current collaboration agreements.

Recent Developments

On January 22, 2016, we closed on the acquisition of a portfolio of generic dosage forms and strengths of Retin-A® (tretinoin), which is a topical prescription acne treatment, from Matawan Pharmaceuticals, LLC, for $415.0 million in cash. We were the authorized generic distributor of these products from 2005 to 2013 before the agreement was terminated. The acquisition complemented our Rx portfolio, furthering our "extended topicals" strategy.

On December 15, 2015, we completed our acquisition of Entocort® (budesonide) capsules, as well as the authorized generic capsules currently marketed by Par Pharmaceuticals, for sale within the U.S., from AstraZeneca plc for $380.2 million in cash. Entocort® is a gastroenterology medicine for patients with mild to moderate Crohn's disease, and the acquisition complemented our Rx portfolio.

Products

Listed below are some of the generic prescription products, including authorized generic and ORx® products, that we manufacture and/or distribute:

Generic Name [1]	Comparative Brand-Name Drug
Adapalene cream	Differin®
Bacitracin ophthalmic ointment	N/A
Benzoyl peroxide 5% - clindamycin 1% gel [2]	BenzaClin™
Budesonide [2]	Entocort® [2]
Clindamycin foam	Evoclin®
Clindamycin phosphate and benzoyl peroxide gel	Duac®
Clobetasol foam, lotion and shampoo	Olux®, Olux-E®, Clobex®
Desonide cream, ointment	Desonate®, Tridesilon®
Dihydroergotamine injection	D.H.E. 45
Halobetasol ointment and cream	Ultravate®
Hydrocortisone suppositories	N/A
Mupirocin ointment	Bactroban®
Nystatin topical powder	Mycostatin®
Permethrin cream	Elimite®
Potassium chloride[2]	Klor-Con®
Tacrolimus	Protopic®
Testosterone 1% gel	Androgel
Testosterone cypionate injection	Depo®, Testosterone
Triamcinolone acetonide nasal spray	Nasacort® AQ
Triamcinolone cream/ointment	Triderm™/Kenalog™

(1) Contains the same active ingredients present in the same dosage form as the comparable brand-name drug
(2) New product launched during the six months ended December 31, 2015.

Net sales related to new products were $43.0 million and $41.0 million for the six months ended December 31, 2015 and December 27, 2014, respectively, and $119.0 million, $106.4 million, and $48.6 million for the fiscal years ended June 27, 2015, June 28, 2014, and June 29, 2013, respectively.

During the six months ended December 31, 2015, we, on our own or in collaboration with partners, received final approval from global health authorities for 10 Rx drug applications, and as of December 31, 2015, we had 59 Rx drug applications pending approval.

Perrigo Company plc - Item 1
Rx Pharmaceuticals

Sales and Marketing

Our customers include major wholesalers, including Cardinal Health, McKesson, and AmerisourceBergen; sourcing groups such as Red Oak; national and regional retail drug, supermarket and mass merchandise chains, including Walgreens/Rite Aid, Walmart, CVS, Kroger, and Safeway; hospitals; and pharmacies. ORx® products are sold to the consumer through the pharmacy counter of predominantly the same retail outlets as our OTC pharmaceutical and nutritional products. In addition, we have a small specialty sales force consisting of representatives who visit healthcare professionals to educate them on the unique clinical characteristics and benefits of our branded products. We are broadening our direct to physician promotional capabilities by expanding our field sales team and other internal resources. Our branded pharmaceutical team continues to invest in the women's health, ophthalmic, and dermatology therapeutic areas.

Competition

The market for Rx products is subject to intense competition from other generic drug manufacturers, brand-name pharmaceutical companies launching their own generic version of their branded products (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 our generic drug manufacturer competitors are Allergan plc, Apotex Corp., Glenmark Generics Inc., Impax Laboratories, Inc., Mylan, Prasco, LLC, Sandoz, Sun Pharmaceuticals, Taro Pharmaceuticals, Teva Pharmaceutical Industries Ltd., Triax Pharmaceuticals, LLC, and Zydus Pharmaceuticals, Inc.

We believe that one of our primary competitive advantages is our ability to introduce difficult to develop and/or manufacture topical and other specialty generic versions to brand-name drug products. Generally, these products are exposed to less competition due to the relatively longer and more expensive development, clinical trial, and approval processes. In addition, we believe we have a favorable competitive position due primarily to our efficient distribution systems, topical production economies of scale, customer service, and overall reputation. See Item 1A. Risk Factors - Risks Related to Operations for more information and risks associated with competition.

SPECIALTY SCIENCES

Overview

The Specialty Sciences segment is comprised primarily of assets focused on the treatment of multiple sclerosis, specifically in connection with the drug Tysabri® (natalizumab). We are entitled to royalty payments from Biogen Idec Inc. ("Biogen") based on its Tysabri® sales in all indications and geographies. We received royalties of 12% on worldwide Biogen sales of Tysabri® from December 18, 2013 through April 30, 2014. Beginning on May 1, 2014, we received, and going forward we will receive, royalties of 18% on annual worldwide Biogen sales of Tysabri® up to $2.0 billion and 25% on annual sales above $2.0 billion. During the six months ended December 31, 2015, Specialty Sciences represented approximately 6% of consolidated net sales.

Competition

Tysabri® is a complex biological product, with the majority of its patents protected through 2024, and is administered under a strict Risk and Evaluation Mitigation Strategy ("REMS") program. In the event that the patent is invalidated or is infringed upon and a biosimilar is introduced, the financial performance of our Specialty Sciences segment would be materially adversely affected. Tysabri® competes with many companies that are working to develop successful new therapies or alternative formulations of products for multiple sclerosis. If any of these competing

products have a similar or more attractive profile in terms of efficacy, convenience, or safety, future sales of Tysabri® could be limited. However, the competition may be limited in its product development as Tysabri® is administered under an FDA-approved REMS programs. See Item 1A. Risk Factors - Risks Related to Operations for related risks.

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Other

OTHER

Overview

We have an Other segment that is comprised of API products, which does not meet the quantitative threshold required to be a separately reportable segment. We develop, manufacture, and market API products, which are used worldwide by both generic and branded pharmaceutical companies. Certain of these ingredients are used in our own pharmaceutical products. The manufacturing of API occurs primarily in Israel with some production in India.

API development is focused on the synthesis of less common molecules for the U.S., European, and other global markets. We commercialize API that are critical to our pharmaceutical customers' existing portfolios and future product launches, working closely with these customers on development processes. We are also focusing manufacturing and development activities on the synthesis of molecules for use in our own OTC and Rx pipeline products. This vertical integration may enable us to be more competitive in the pricing of our product lines.

Because our API customers depend on high quality supply and regulatory support, we focus on rigorous quality assurance, quality control, and regulatory compliance as part of our strategic positioning. Our quality system is designed to comply with the regulatory requirements of the FDA, the European Medicines Agency ("EMA"), and other regulatory agencies such as the Australian Therapeutic Goods Administration. We are regularly inspected by various regulatory authorities and customers.

Recent Developments

We are pursuing the sale of our API business based in India and expect the sale to take place during 2016. As of December 31, 2015, we reclassified India's net assets to "held for sale" as discussed in Item 8. Note 9.

Competition

Since other manufacturers of API typically do not offer all of the same product lines or serve all of the same markets as we do, the business competes on a product-by-product basis with a number of different competitors. Our API category is subject to increased price competition from other manufacturers of API located mostly in India, China, and Europe. See Item 1A. Risk Factors - Risks Related to Operations for information and risks associated with competition.

INFORMATION APPLICABLE TO ALL REPORTABLE SEGMENTS

Research and Development

R&D is a key component of our business strategy and, while managed centrally, is performed in various locations in the countries in which we operate. While we conduct a significant amount of our own R&D, we also enter into strategic alliance agreements to obtain the rights to manufacture and/or distribute new products.

R&D spending was $88.2 million and $89.8 million for the six months ended December 31, 2015, and December 27, 2014, respectively, and $187.8 million, $152.5 million, and $115.2 million for the fiscal years ended June 27, 2015, June 28, 2014, and June 29, 2013, respectively. In addition, we wrote off in-process research and development from previous acquisitions totaling $6.0 million during the fiscal year ended June 28, 2014 and $9.0 million during the fiscal year ended June 29, 2013 due to changes in the projected development and regulatory timelines for various

projects.

The six months ended December 31, 2015 included incremental R&D expense due to the Omega acquisition. The six months ended December 27, 2014 included a $10.0 million payment made in connection with our entry into a collaboration arrangement. The fiscal year ended June 27, 2015 also included incremental R&D expense due to the Omega acquisition, as well as the payment made in relation to the collaboration arrangement noted above, and an R&D contractual arrangement under which we funded $18.0 million of R&D. The fiscal year ended June 28, 2014 included incremental R&D expense attributable to the Sergeant's Pet Care Products, Inc. ("Sergeant's") and Velcera Inc. ("Velcera") acquisitions that closed during the previous fiscal year, as well as R&D

expense related to the ELND005 Phase 2 clinical program in collaboration with Transition Therapeutics, Inc. ("Transition"), which we acquired from Elan. We ended our collaboration with Transition during the third quarter of the fiscal year ended June 28, 2014 and are no longer responsible for ongoing development activities and costs associated with ELND005. The fiscal year ended June 29, 2013 included incremental R&D expenses attributable to the acquisition of Sergeant's, Velcera, and Rosemont Pharmaceuticals Ltd. See Item 8. Note 2 and Item 8. Note 17 for more information on the acquisitions, collaboration arrangement, and R&D contractual arrangement noted above.

We anticipate that R&D expenditures will increase in dollar terms but will remain relatively flat to slightly higher as a percentage of net sales for the foreseeable future as we continue to cultivate our presence in the Rx-to-OTC switch and generic pharmaceutical markets, and develop our internal R&D capabilities. See Item 1A. Risk Factors - Risks Related to Operations for risks associated with innovation and R&D.

Trademarks and Patents

While we own certain trademarks and patents, neither our business as a whole, nor any of our segments, is materially dependent upon our ownership of any one trademark or patent or group of trademarks or patents.

Materials Sourcing

Affordable high quality raw materials and packaging components are essential to all of our business units due to the nature of the products we manufacture. Raw materials and packaging components are generally available from multiple suppliers. Supplies of certain raw materials, bulk tablets, and components are limited, or are available from one or only a few suppliers. While we have the ability to manufacture and supply certain API for our OTC and Rx products, an increasing number of components and finished goods are purchased rather than manufactured because of temporary production limitations, FDA restrictions, economic conditions, or other factors.

Historically, we have been able to react effectively to situations that require alternate sourcing. Should alternate sourcing be necessary, FDA requirements placed on products approved through the ANDA or NDA process could substantially lengthen the approval of an alternate source and adversely affect financial results. We believe we have good, cooperative working relationships with substantially all of our suppliers and have historically been able to capitalize on economies of scale in the purchase of materials and supplies due to our volume of purchases. See Item 1A. Risk Factors - Risks Related to Operations for risks associated with materials sourcing.

Manufacturing and Distribution

Our primary manufacturing facilities are in the U.S. and Israel. We also have secondary manufacturing facilities in the U.K., Belgium, France, Germany, Austria, Mexico, Australia, and India, along with a joint venture in China. See Item 1A. Risk Factors - Risks Related to Operations for risks associated with our manufacturing facilities. We supplement our production capabilities with the purchase of products from outside sources. The capacity of some facilities may be fully utilized at certain times for various reasons, such as customer demand, the seasonality of the cough/cold/flu, allergy, or flea and tick seasons, and new product launches. We may utilize available capacity by performing contract manufacturing for other companies. We have logistics facilities in the U.S., Israel, Mexico, Australia, and numerous locations throughout Europe. We use contract freight and common carriers to deliver our products.

Significant Customers

Our primary customer base aligns with the concentration of large drug retailers in the current global retail drug industry marketplace. Walmart is our largest customer and accounted for 13% of consolidated net sales for the six months ended December 31, 2015, 15% for the fiscal year ended June 27, 2015, and 19% for both the fiscal years ended June 28, 2014 and June 29, 2013. Sales to Walmart are primarily in the CHC segment. As a percentage of our total U.S. OTC sales, our sales to Walmart closely align with Walmart's U.S. retail market share. While we do not anticipate a change in the foreseeable future, should our current relationship with Walmart change adversely, the resulting loss of business could have a material adverse impact on our consolidated and CHC segment operating results and financial position. In addition, while no other customer individually comprises more than 10% of total net sales, we do have other significant customers. We believe we generally have good relationships with all of our customers. See Item 1A. Risk Factors - Risks Related to Operations for risks associated with customers.

Seasonality

Historically we have been impacted by seasonal demand and consumer dynamics in the retail environment in which our customers operate. Sales of OTC pharmaceutical products in the CHC segment are typically subject to seasonal demands for cough/cold/flu products from September through March and allergy products from April through September. Our BCH segment's sales are also impacted by seasonality and tend to peak in April through June due to increased demand for seasonal health and wellness products. In addition, our animal health products are subject to seasonal demand for flea and tick products that typically peaks during the warmer weather months, from March through June. Our Rx, Specialty Sciences, and Other segments' sales are not generally impacted by seasonal conditions. Accordingly, operating results for the six months ended December 31, 2015 are not necessarily indicative of the results that may be expected for a full year.

Environmental

We are subject to various environmental laws and regulations. We have made, and continue to make, expenditures necessary to comply with applicable environmental laws, but do not believe that the costs for complying with such laws and regulations have been or will be material to our business. We do not have any material remediation liabilities outstanding.

While we believe that climate change could present risks to our business, including increased operating costs due to additional regulatory requirements, physical risks to our facilities, water limitations, and disruptions to our supply chain, we do not believe these risks are material to our business in the near term.

Corporate Social Responsibility

We are committed to doing business in an ethical manner. We also have a long history of environmentally sound and efficient operations, safe and healthy working conditions, and active participation in the communities where we are located. As reflected in our Corporate Social Responsibility Commitment Statement available on our website, we remain committed to:

- Helping consumers access safe, effective and affordable healthcare products;
- Strong corporate governance;
- Complying with regulatory and legal requirements;
- Demonstrating environmental stewardship;

- Continuously improving packaging sustainability;
- Protecting human rights of our global employees and challenging our partners to do the same;
- Providing a safe and healthy work environment for our employees;
- Diversity and gender equality of our Board of Directors, management, and employees; and
- Establishing effective community partnerships.

Through these efforts, we strive to minimize our impact on the environment, drive responsible business practices, and ensure the welfare of our employees, their families, and the communities in which we operate now and into the future.

GOVERNMENT REGULATION AND PRICING

The manufacturing, processing, formulation, packaging, labeling, testing, storing, distributing, advertising, and sale of our products are subject to regulation by a variety of agencies in the localities in which our products are sold. In addition, we manufacture and market certain of our products in accordance with standards set by various organizations. We believe that our policies, operations, and products comply in all material respects with existing regulations to which we are subject. See Item 1A. Risk Factors - Risks Related to Operations for related risks.

United States Regulation

U.S. Food and Drug Administration

The FDA has jurisdiction over our ANDA, NDA, Drug Efficacy Implementation, and OTC monograph drug products, infant formulas, dietary supplements, food products, and medical devices. The FDA’s jurisdiction extends to the manufacturing, testing, labeling, packaging, storage, distribution, and promotion of these products. We are committed to consistently providing our customers with high quality products that adhere to "current Good Manufacturing Practices" ("cGMP") regulations promulgated by the FDA.

OTC and Rx Pharmaceuticals

All facilities where Rx and OTC drugs are manufactured, tested, packaged, stored, or distributed for the U.S. market must comply with FDA cGMPs and regulations promulgated by competent authorities in the countries, states and localities where the facilities are located. All of our drug products are manufactured, tested, packaged, stored, and distributed according to cGMP regulations. The FDA performs periodic audits to ensure that our facilities remain in compliance with all appropriate regulations.

Many of our OTC pharmaceutical products are regulated under the OTC monograph system and subject to certain FDA regulations. Under this 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. Drug products marketed under the OTC monograph system must conform to specific quality, formula, and labeling requirements, including permitted indications, required warnings and precautions, allowable combinations of ingredients, and dosage levels. It is generally less costly to develop and bring to market a product regulated under the OTC monograph system.

We also market generic prescription drugs and other products that have switched from prescription to OTC status. Prior to commercial marketing, these products require approval by the FDA of an ANDA or NDA that provides information on chemistry, manufacturing controls, clinical safety, efficacy and/or bioequivalence, packaging, and labeling. While the development process for a generic drug generally requires less time and expense than the development process for a new drug, the size and duration of required studies can vary greatly. The current average ANDA approval time is approximately 42 months from the date an ANDA is submitted. NDA approvals are typically achieved in 12 months or less. Changes to a product marketed under an ANDA or NDA are governed by specific FDA regulations and guidelines that define when proposed changes can be implemented and whether prior FDA notice and/or approval is required.

Under the Federal Food, Drug and Cosmetic Act, as amended ("FFDCA") (the Hatch-Waxman amendments), a company submitting an NDA can obtain a three-year period of marketing exclusivity for a prescription or OTC

product if it performs a clinical study that is essential to FDA approval. Longer periods of exclusivity are possible for new chemical entities, orphan drugs (those designated under section 526 of the FFDCA) and drugs under the Generating Antibiotic Incentives Now Act. During this exclusivity period, the FDA cannot approve any ANDAs for a similar or equivalent generic product, which can preclude us from marketing a similar product during this period. A company may obtain an additional six months of exclusivity if it conducts pediatric studies requested by the FDA on the product. This exclusivity can delay both the FDA approval and sales of certain products.

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Regulation

A company may be entitled to a 180-day generic exclusivity period for certain products. This exclusivity period often follows a patent certification and litigation process whereby the product innovator may sue for infringement. The legal action does not ordinarily result in material damages, but it generally triggers a statutorily mandated delay in FDA approval of the ANDA for a period of up to 30 months from when the innovator was notified of the patent challenge.

The Food and Drug Administration Safety and Innovation Act ("FDASIA") was signed into law on July 9, 2012. The law established, among other things, new user fee statutes for generic drugs and biosimilars, FDA authority concerning drug shortages, changes to enhance the FDA's inspection authority of the drug supply chain, and a limited extension of the 30-month stay provision described above. The FDASIA also reduced the time required for FDA responses to generic-blocking citizen petitions. We implemented new systems and processes to comply with the new facility self-identification and user fee requirements of the FDASIA, and we monitor facility self-identification and fee payment compliance to mitigate the risk of potential supply chain interruptions or delays in regulatory approval of new applications.

The U.S. government's Federal Drug Supply Chain Security Act ("DSCSA") requires development of an electronic pedigree to track and trace each prescription drug at the salable unit level through the distribution system, which will be effective incrementally over a 10-year period. The serialization of all Rx products distributed in the U.S. needs to be completed by November 27, 2017, with the requirement for tracking the products commencing on November 27, 2023. Requirements for the tracing of products at the lot level through the pharmaceutical distribution supply chain went into effect on January 1, 2015 for manufacturers, wholesale distributors, and re-packagers, and on July 1, 2015 for dispensers.

Infant Formula and Foods

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

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

Before marketing a particular infant formula, the manufacturer must provide regulatory agencies assurance of the nutritional quality of that particular formulation consistent with the FDA’s labeling, nutrient content, and manufacturer quality control requirements. A manufacturer must notify the FDA at least 90 days before the marketing of any infant formula that differs fundamentally in processing or in composition from any previous formulation produced by the manufacturer. We actively monitor this process and make the appropriate adjustments to remain in compliance with recent FDA rules regarding cGMP, quality control procedures, quality factors, notification requirements, and reports and records for the production of infant formulas.

In addition, the FFDCA requires infant formula manufacturers to test product composition during production and shelf-life; to keep records on production, testing, and distribution of each batch of infant formula; to use cGMP and quality control procedures; and to maintain records of all complaints and adverse events, some of which may reveal

the possible existence of a health hazard. The FDA conducts yearly inspections of all facilities that manufacture infant formula, inspects new facilities during early production runs, and collects and analyzes samples of infant formula.

Our infant and toddler foods are subject to the Food Safety Modernization Act ("FSMA"), which protects the safety of U.S. foods by mandating comprehensive, prevention-based controls within the food industry. Under FSMA, the FDA has mandatory recall authority for all food products and greater authority to inspect food producers and is taking steps toward product tracing to enable more efficient product source identification in the event of a safety issue.

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Regulation

Dietary Supplements Manufactured in the U.S.

The Dietary Supplement Health and Education Act of 1994 ("DSHEA") amended the FFDCA to, among other things:

- Define dietary supplements and dietary ingredients;
- Require ingredient and nutrition labeling for dietary supplements;
- Permit "structure/function" statements for dietary supplements;
- Permit the display of certain published literature where supplements are sold;
- Authorize the FDA to establish GMPs specifically for dietary supplements, which it did in 2007; and
- Require the submission of New Dietary Ingredient notifications to the FDA.

Under DSHEA, the FDA specified that all supplements must bear a "Supplement Facts" box, which lists all of the supplement's dietary ingredients using FDA-specified nomenclature. DSHEA also permits dietary supplements to bear statements:

- Claiming a benefit related to a classical nutrient deficiency disease, provided the prevalence of the disease in the U.S. is disclosed;
- Describing the role of a nutrient or dietary ingredient intended to affect the structure or function in humans;
- Characterizing the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function; and
- Describing general well-being from consumption of a nutrient or dietary ingredient.

We are 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.

The DSHEA requires that the FDA be notified at least 75 days in advance of the introduction of a dietary supplement that contains a new dietary ingredient that was not marketed before October 15, 1994. The notification must provide information establishing that the dietary supplement containing the dietary ingredient will be reasonably expected to be safe.

Our U.S. dietary supplement facilities have been inspected by the FDA and are operating in compliance with dietary supplement cGMPs.

Active Pharmaceutical Ingredients

We develop and manufacture API in Israel and India for export to the U.S. and other global markets. Before API can be commercialized in the U.S., we must submit a drug master file ("DMF") that provides the proprietary information related to the manufacturing process. The FDA inspects the manufacturing facilities to assess cGMP compliance, and the facilities and procedures must be cGMP compliant before API may be exported to the U.S.

The facilities and products are subject to regulation by the applicable regulatory bodies in the place of manufacture as well as the regulatory agency in the country from which the product is exported. Our Israeli facility has been approved by the U.S. FDA, Israel Ministry of Health ("IMOH"), Federal Commission for the Protection against Sanitary Risks of Mexico, Pharmaceutical and Medical Devices Agency of Japan, and the Korean Food and Drug Administration and

has received GMP certification from IMOH. Our India facility has been inspected by the U.S. FDA and has received GMP certification from the Indian FDA.

For API exported to European markets, we submit a European DMF and, where applicable, obtain a certificate of suitability from the European Directorate for the Quality of Medicines. The manufacturing facilities and production procedures for API marketed in Europe must meet EU-GMP and European Pharmacopeia standards.

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Regulation

U.S. Department of Agriculture

The Organic Foods Production Act enacted under Title 21 of the 1990 Farm Bill established uniform national standards for the production and handling of foods labeled as "organic." Our infant formula manufacturing sites in Vermont and Ohio adhere to the standards of the U.S. Department of Agriculture ("USDA") National Organic Program for the production, handling, and processing to maintain the integrity of organic products. Our infant formula manufacturing sites in Vermont and Ohio are USDA-certified, enabling them to produce and label organic products for U.S. and Canadian markets.

U.S. Environmental Protection Agency

The U.S. Environmental Protection Agency ("EPA") is the main regulatory body in the United States for veterinary pesticides. The EPA's Office of Pesticide Programs is responsible for the regulation of pesticide products applied to animals. All manufacturers of animal health pesticides must show that their products will not cause “unreasonable adverse effects to man or the environment” as stated in the Federal Insecticide, Fungicide, and Rodenticide Act. Within the United States, pesticide products that are approved by the EPA must also be approved by individual state pesticide authorities before distribution in that state. Post-approval monitoring of products is required, with reports provided to the EPA and some state regulatory agencies.

U.S. Drug Enforcement Administration

The U.S. Drug Enforcement Administration ("DEA") regulates certain drug products containing controlled substances, such as morphine, hydromorphone, opium, and List I chemicals, such as pseudoephedrine, pursuant to the federal Controlled Substances Act ("CSA"). The CSA and DEA regulations impose registration, security, record keeping, reporting, storage, manufacturing, distribution, importation and other requirements upon legitimate handlers under the oversight of the DEA. The DEA categorizes controlled substances into Schedules I, II, III, IV, or V, with varying qualifications for listing in each schedule. We are subject to the requirements regarding the controlled substances in Schedules II - V and the List I chemicals. Our facilities that manufacture, distribute, import, or export any controlled substances must register annually with the DEA.

The DEA inspects all manufacturing facilities to review security, record keeping, reporting, and handling prior to issuing a controlled substance registration, and it also periodically inspects facilities for compliance with the CSA and its regulations. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action, such as civil penalties, refusal to renew necessary registration, or the initiation of proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution. We are also subject to state legislation regulating the manufacture and distribution of certain products.

Medicaid Drug Rebate Program and Other Drug Pricing Programs

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

The Medicaid rebate agreement provides that the drug manufacturer will remit rebates to each state Medicaid agency on a quarterly basis based on pricing data reported by the manufacturer to CMS, including Average Manufacturer Price ("AMP") and, in the case of innovator products, Best Price ("BP"). We report AMP on a monthly and quarterly basis and BP on a quarterly basis. The minimum rebate amounts due are as follows: for noninnovator products, in general generic drugs marketed under ANDAs, the rebate amount is 13% of the AMP for the quarter; for innovator products, in general brand-name products marketed under NDAs, the rebate amount is the greater of 23.1% of the AMP for the quarter or the difference between such AMP and the BP for that same quarter. Manufacturers also pay an additional rebate on innovator drugs where price increases since launch have

outpaced inflation. Beginning with the first quarter of 2017, an additional rebate is due for noninnovator products, which is calculated somewhat differently from the innovator product additional rebate.

Under health reform legislation enacted in 2010 (the "Health Reform Law"), CMS is preparing to use AMPs to calculate a type of U.S. federal ceiling on reimbursement rates to pharmacies for multiple source drugs under the Medicaid program, known as the federal upper limit ("FUL"). CMS has been publishing draft FULs based on reported AMPs. CMS also surveys and publishes retail community pharmacy acquisition cost information to provide state Medicaid agencies with a basis for comparing their own reimbursement and pricing methodologies and rates. On February 1, 2016, CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate program under the Health Reform Law. This regulation becomes effective on April 1, 2016.

U.S. law also requires that a company that participates in the Medicaid rebate program report average sales price ("ASP") information to CMS for each calendar quarter for certain categories of drugs that are paid under Part B of the Medicare program. CMS uses these submissions to determine payment rates for drugs under Medicare Part B.

Pricing and rebate calculations are governed by statutory and regulatory requirements that are complex, vary among products and programs, can change over time, and are subject to interpretation by us, governmental or regulatory agencies, and the courts. In the case of the Medicaid rebate program, if we become aware of errors in our prior price submissions, or a prior BP submission needs to be updated due to late arriving data, we must resubmit the updated data for a period not to exceed 12 quarters from the quarter in which the data originally was due. Such restatements and recalculations increase our cost of compliance with the Medicaid rebate program, and corrections can result in an overage or underage of our rebate liability for past quarters, depending on the nature of the correction.

U.S. law requires any company that participates in the Medicaid rebate program to also participate in the Public Health Service’s 340B drug pricing program in order for federal funds to be available for the manufacturer’s drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. The ceiling price is derived from the data the manufacturer reports under the Medicaid rebate program and therefore any changes to statutory or regulatory requirements applicable to the Medicaid price figures may impact the 340B ceiling price calculation as well. 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

U.S. law also requires any company that participates in the Medicaid rebate program and Medicare Part B and that wants its covered drugs paid for by certain federal agencies and grantees participate in the Department of Veterans Affairs ("VA") Federal Supply Schedule (“FSS”) pricing program. Accordingly, we must enter into an FSS contract with the VA, whereby our "covered drugs" are available to the VA, the Department of Defense, the Public Health Service, and the Coast Guard at pricing that is capped pursuant to a statutory Federal Ceiling Price (“FCP”).

In addition to the Veterans Health Care Act of 1992 requirements, FSS contracts include extensive disclosure and certification requirements and standard government terms and conditions with which we must comply. We also have a Section 703 Agreement under which we pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. See Item 1A. Risk Factors - Risks Related to Operations for risks related to the above-mentioned programs.

Other U.S. Regulations and Organizations

We are subject to various other national, state, non-governmental, and local agency rules and regulations. Compliance with the laws and regulations regarding the manufacture and sale of our current products and the discovery, development, and introduction of new products requires substantial effort, expense and capital investment. Other regulatory agencies, organizations and legislation that may impact our business include, but are not limited to:

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- Physician Payment Sunshine Act - This act requires certain pharmaceutical manufacturers to engage in extensive tracking of payments or transfers of value to physicians and teaching hospitals, maintenance of a payment database and public reporting of the payment data.

- Foreign Corrupt Practices Act of 1977 ("FCPA") - This act and other similar anti-bribery laws prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties or international organizations with the intent to obtain or retain business or seek a business advantage.

- Federal Trade Commission ("FTC") - This agency oversees the advertising and other promotional practices of consumer products marketers. The FTC considers whether a product's claims are substantiated, truthful and not misleading. The FTC also reviews mergers and acquisitions of companies exceeding specified thresholds and investigates certain business practices relevant to the healthcare industry.

- NSF International ("NSF") - The NSF is an independent, not-for-profit, non-governmental organization that provides risk management services for public health and safety. Many of our dietary supplement products are certified under NSF/ANSI Standard 173.

- International Organization for Standardization ("ISO") - The ISO Standards specify requirements for a Quality Management System that demonstrates the ability to consistently provide products that meet customer and applicable regulatory standards and includes processes to ensure continuous improvement. Our infant formula manufacturing sites are ISO 9001-2008 Certified for Quality Management Systems. ISO inspections are conducted at least annually.

- United States Pharmacopeial Convention, Inc. ("USP") - The USP is a non-governmental, standard-setting organization. By reference, the FFDCA incorporates the USP quality and testing standards and monographs as the standard that must be met for the listed drugs, unless compliance with those standards is specifically disclaimed on the product's labeling. USP standards exist for most Rx and OTC pharmaceuticals and many nutritional supplements. The FDA typically requires USP compliance as part of cGMP compliance.

- Health Insurance Portability and Accountability Act ("HIPAA") - We could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA.

- Consumer Product Safety Commission ("CPSC") - The CPSC has published regulations requiring child resistant packaging on certain products including pharmaceuticals and dietary supplements. The manufacturer of any product that is subject to any CPSC rule, ban, standard or regulation must certify that, based on a reasonable testing program, the product complies with CPSC requirements.

- Other State Agencies - We are subject to regulation by numerous other state health departments, insurance departments, boards of pharmacy, state controlled substance agencies, state consumer health and safety regulations, and other comparable state agencies, each of which have license requirements and fees that vary by state.

Regulation Outside the U.S.

We develop and manufacture products and market third-party manufactured products in regions outside the U.S., including Russia, South Africa, Israel, Mexico, and Australia, as well as countries in Asia, South America, the Middle East, and Eastern and Western Europe, each of which has its own regulatory environment. The majority of our sales

outside the U.S. are in the following categories: OTC/Rx pharmaceuticals, medical devices, dietary supplements (including VMS) and cosmetics.

Perrigo Company plc - Item 1
Regulation

European Union

OTC and Rx Pharmaceuticals

The European pharmaceutical industry is highly regulated and much of the legislative and regulatory framework is driven by the European Parliament and the European Commission. This has many benefits, including the potential to harmonize standards across the complex European market. However, obtaining regulatory agreement across member states presents complex challenges that can lead to delays in the regulatory process.

In the European Union ("EU"), as well as many other locations around the world, the manufacture and sale of medicinal products is regulated in a manner substantially similar to that of the U.S. requirements, which generally prohibit the handling, manufacture, marketing, and importation of any medicinal product unless it is properly registered in accordance with applicable law. The registration file relating to any particular product must contain data related to product efficacy and safety, including results of clinical testing and / or 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 if it is manufactured or marketed other than in accordance with registration conditions.

Between 1995 and 1998, the over-arching legislation that governs medicinal products was revised in an attempt to simplify and harmonize product registration. This revised legislation introduced the mutual recognition procedure ("MRP"), whereby after approval of a marketing authorization by regulatory authorities in the reference member state ("RMS"), additional marketing authorizations could be submitted to other concerned member states to obtain a product license. In November 2005, the medicinal product legislation was further revised to introduce the decentralized procedure ("DCP") whereby marketing authorizations are submitted simultaneously to the RMS and select concerned member states. In 2005, the EMA also opened up the centralized procedure to sponsors of marketing authorizations for generic medicinal products. Unlike the MRP and DCP, the centralized procedure results in a single marketing authorization and product labeling across all member states that will allow a sponsor to file for individual country reimbursement and make the medicine available in all the EU countries listed on the application. Marketing authorizations and subsequent product licenses are granted to applicants only after the relevant health authority issues a positive assessment of quality, safety and efficacy of the product.

In addition to obtaining marketing authorization for each product, all member states require that a manufacturer's facilities obtain approval from an EU Regulatory Authority. The EU has a code of GMP that each manufacturer must follow and comply with. Regulatory authorities in the EU may conduct inspections of the manufacturing facilities to review procedures, operating systems, and personnel qualifications. We believe that our policies, operations and products comply in all material respects with existing regulations to which our operations are subject.
Some elements of the European Falsified Medicines Directive (the "Directive") were enacted into national laws during 2013. The provisions of the Directive are intended to reduce the risk of counterfeit medicines entering the supply chain and also to ensure the quality of API manufactured outside of the EU. The Directive required the serialization of all Rx and some OTC products, similar to the DSCSA in the U.S.
In the EU, member states regulate the pricing of prescription medicinal products, and in some cases, the formulation and dosing of products. This regulation is handled by individual member state national health services. These individual regulatory bodies can result in considerable price differences and product availability among member states. The implementation of tendering systems for the pricing of pharmaceuticals in several countries generally impacts drug pricing for generics; generally "tendering" refers to a system that requires bids to be submitted to the government by competing manufacturers to be the exclusive, or one of a few, suppliers of a product in a particular country.

Data exclusivity provisions exist in many countries, although the application is not uniform. 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.

Perrigo Company plc - Item 1
Regulation

The requirements deriving from European pharmacovigilance legislation are constantly expanding due to increasing guidance on good vigilance practices and increased communication on inspectors' expectations. Pharmacovigilance fee legislation became effective in late 2014 to support health authority assessment of pharmacovigilance safety evaluation reports, study protocols for post authorization safety studies and referrals. Once approved, the advertising of pharmaceuticals in the EU is governed by national regulations and guidelines. Within certain member states this is overseen by a self-certification process whereas in others national governance bodies approve material prior to release.

Medical Devices

The EU has enacted into law numerous directives and adopted many harmonizing standards pertaining to a wide range of industrial products, including medical devices. Medical devices that comply with the requirements of applicable directives are entitled to bear the CE marking of conformity, which indicates that the device conforms to the applicable requirements of the directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a Notified Body, an organization accredited by a member state. Assessment by a Notified Body includes an audit of the manufacturer's quality system and may also include specific testing of the product. This assessment is a prerequisite for a manufacturer to commercially distribute the product throughout the EU.

Dietary Supplements (including VMS)

Dietary supplements are subject to several regulations that inform the selection of ingredient levels and how products can be described on packaging and in advertising. These regulations include: Food Supplements Directive 2002/46/EC, Food Information to Consumers Regulation (EU) No 1169/2011, Permitted Vitamins and Minerals Regulation (EC) 1170/2009, Food Additives Regulation (EC) 1333/2008, and Nutritional & Health Claims Regulation (EC) No 1924/2006, and starting in July 2016, the Foods Intended for Particular Nutritional Uses Directive 2009/39/EC & Regulation (EU) 609/2013.

EU rules on nutrition and health claims, which were established by Regulation EC 1924/2006, apply to any nutritional or health claim by a manufacturer. The objective of the regulation is to ensure that claims made in food labeling or advertising are clear, accurate and based on scientific evidence. The European Food Safety Authority, an advisory panel to the European Commission, performs all scientific assessments of health claims on food and supplement labels. An EU register of nutrition and health claims exists to document approved, pending, and rejected claims.

Cosmetics

Cosmetic products in the EU market must comply with Regulation EC No. 1223/2009. This regulation requires manufacturers to prepare a product safety report prior to placing a cosmetic product in the market. In addition, for each cosmetic product placed in the market, a "responsible person" must be designated to oversee compliance with the regulation's reporting requirements. Commission Regulation EU No. 655/2013 establishes the common criteria and justification for claims to be used in the packaging and advertising of cosmetics products.

Employees

As of December 31, 2015 we had approximately 13,300 full-time and temporary employees worldwide, of which approximately 2,700 were covered by collective bargaining agreements. The majority of our employees covered by collective bargaining agreements are located in Europe, Mexico, and Israel. We consider our employee relations

generally satisfactory.

Available Information

Our principal executive offices are located at the Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland and our administrative offices are located at 515 Eastern Avenue, Allegan, Michigan 49010. Our telephone number is +353 1 7094000. Our website address is www.perrigo.com, where we make available free of charge our reports on Forms 10-KT, 10-K, 10-Q and 8-K, including 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 www.sec.gov and www.isa.gov.il.

ITEM 1A. RISK FACTORS

Risks Related to Operations

If we do not continue to rapidly develop, manufacture, and market innovative products that meet customer demands, we may lose market share and our net sales may be negatively impacted.

Our continued growth is due in large part to our ability to rapidly develop, manufacture, and market products that meet customer requirements for quality, safety, efficacy, and cost effectiveness. Continuous introductions of new products and product categories are critical to our business. If we do not continue to develop, manufacture, and market new products, we could lose market share, and our net sales may be negatively impacted. See Item 1. Business - Research and Development for more information.

- We maintain a diversified product line to function as a primary supplier for our customers. Capital investments are driven by growth, technological advancements, cost improvement and the need for manufacturing flexibility. Our estimates of future capital expenditures could vary materially due to the uncertainty of these factors. In addition, if we fail to stay current with the latest manufacturing, information and packaging technology, we may be unable to competitively support the launch of new product introductions.

- Our product margins may decline over time due to our products' aging life cycles, changes in consumer choice, changes in competition for our existing products, or the introduction of next generation innovative products; therefore, new product introductions are necessary to maintain our current financial condition. If we are unable to continue to create new products, we may lose market share or experience pricing pressure, and our net sales may be negatively impacted.

- We must prove that the ANDA regulated drug products in our CHC and Rx segments are bioequivalent to their branded counterparts, which requires bioequivalence studies, and in the case of topical products, even more extensive clinical endpoint trials to demonstrate the efficacy. The development and commercialization process, particularly with respect to innovative products, is both time consuming and costly, and subject to a high degree of business risk. Products currently under development, if and when fully developed and tested, may not perform as expected, may not pass required bioequivalence studies, or may be the subject of intellectual property challenges. Necessary regulatory approvals may not be obtained in a timely manner, if at all, and we may not be able to successfully and profitably produce and market such products. This could negatively impact our net sales.

- Our ability to attract and retain scientists proficient in emerging delivery forms and/or contracting with a third party in order to generate new products of this type is critical to our long-term plans. If we fail to attract and retain this talent, our long-term sales growth and profit could be adversely impacted.

- Even upon the successful development of a product, our customer's failure to launch a product successfully, or delays in manufacturing, could adversely affect our operating results. In addition, the FDA or similar regulatory agency could impose higher standards and additional requirements, such as requiring more supporting data and clinical data than previously required, in order to gain regulatory clearance to launch new formulations into the market, which could negatively impact our future net sales.

We contract with clinical research organizations ("CROs") to conduct various studies that are used to support our new product development program. During the third quarter of our fiscal year ended June 29, 2013, certain of these CROs began bankruptcy or receivership proceedings, including PRACS Institute, LLC, PRACS Institute Canada B.C. Ltd., Comprehensive Clinical Development, Inc., and their related entities. It is uncertain what impact these insolvency proceedings may have on their ability to deliver their study results to us or on our ability to rely on their research. To the extent these CROs cannot deliver their study results to us or we cannot rely, in whole or in part, on the research conducted by them, we may be required to delay the launch of new products, which could have a material adverse impact on our future

operating results. The FDA may be limited in its ability to inspect CROs' study facilities or to gain access to source study documents, which may result in us having to repeat biostudies. If these scenarios occur, it could result in approval delays for new products, which could adversely impact our future net sales. These situations are unique, and we are unable to predict the FDA's position on the studies conducted by these now bankrupt CROs.

Our CHC and BCH segments are impacted by changes in consumer preferences. If we are unable to adapt to these changes, we may lose market share and our net sales may be negatively impacted.

While the market for store brand products has grown in recent years, there can be no assurance that the pace of this growth will continue. Additionally, consumer preferences related to health and nutritional concerns may change, which could negatively impact demand for our CHC and BCH products or cause us to incur additional costs to change our products or product packaging.

- The future growth and stability of U.S. store brand market share will be impacted, in part, by general economic conditions, which can influence consumers to switch to and from store brand products. Our CHC segment sales could be negatively affected if economic conditions improve and consumers return to purchasing higher-priced brand-name products. Conversely, while store brand products present an alternative to higher-priced branded products, if economic conditions deteriorate, our CHC segment sales could be negatively impacted if consumers forgo obtaining healthcare or reduce their healthcare spending.

- Our BCH segment's success is dependent on the continued growth in demand for its lifestyle products, which include weight-loss products and various dietary supplements. If demand for these products decreases, our BCH segment's results of operations would be negatively impacted.

- Our CHC customers may request changes in packaging to meet consumer demands, which could cause us to incur inventory obsolescence charges and redesign costs, which in turn would negatively impact our CHC segment's results of operations.

- Our infant formula product category within our CHC segment is subject to changing consumer preferences and health and nutrition-related concerns. Our business depends, in part, on consumer preferences and choices, including the number of mothers who choose to use infant formula products rather than breastfeed their babies. To the extent that private, public, and government sources may promote the benefits of breastfeeding over the use of infant formula, there could be a reduced demand for infant formula products. We could also be adversely impacted by an increase in the number of families that are provided with infant formula by the U.S. federal government through the Women, Infants and Children program, as we do not participate in this program.

We face risks associated with the successful integration of our recently-acquired Omega business.

As described in Item 1. Business - Major Recent Developments, we closed on the Omega acquisition on March 30, 2015. In addition to the risks mentioned under "We may not realize the benefits of business acquisitions and divestitures we enter into, which could have a material adverse effect on our operating results", the Omega acquisition exposes us to a number of business, financial, and competitive risks, including:

- The Omega acquisition represents a major shift in our business, both geographically, as our business is now more heavily concentrated in European markets than before, and operationally, as the Omega business sells well-known branded products using a large sales force. These changes may present challenges and risks related to, among other things, our attempt to create synergies with Omega. There is no assurance that we will be able to successfully integrate Omega or otherwise realize the expected benefits of the Omega acquisition.

- Our success in the European markets in which Omega operates will depend on a number of factors, such as:
- Our ability to commercialize new products;
- Our ability to adapt to changes in economic and political conditions;
- Fluctuations in the value of foreign currencies and interest rates;

Perrigo Company plc - Item 1A
Risk Factors

- Compliance with differing regulatory and legal requirements, including tax laws, trade laws, labor, safety, local content, consumer protection regulation, and import or export licensing requirements; and
- Consistency and transparency of foreign tax systems, transfer pricing stability across jurisdictions, and our ability to reinvest earnings and cash as appropriate.

Many of these factors are beyond our control, and any one of them could result in increased costs, decreased net sales, and diversion of management's time and energy, any or all of which could materially impact our business, financial condition, and results of operations.

- While Omega has not historically been subject to U.S. laws and regulations, such as the FCPA, it has been subject to a wide range of European laws and regulations, including the U.K. Bribery Act of 2010. The comparable U.S. laws and regulations to which Omega is now subject may differ from those to which Omega was historically subject. Therefore, it is possible that certain Omega sales or other activities that were permitted while Omega was an independent company may no longer be permitted. While we are putting into place compliance processes and controls intended to ensure compliance with U.S. and global laws that now apply to Omega, if Omega's operations fail to comply with such laws and regulations, we could be subject to governmental investigations, legal or regulatory proceedings, substantial fines, and/or other legal or equitable penalties.

We operate in a highly regulated industry, and any inability to timely meet current or future regulatory requirements could have a material adverse effect on our business, financial position, and operating results.

We are subject to the regulations of a variety of U.S. and non-U.S. agencies related to the manufacturing, processing, formulation, packaging, labeling, testing, storing, distribution, advertising, and sale of our products as described in detail in Item 1. Business - Government Regulation and Pricing. Government regulation in the markets in which we operate could impact our business, and our future results could be adversely affected by changes in such regulations or policies. Below are some of the ways in which government regulation could impact our business and/or financial results:

- We must obtain approval from the appropriate regulatory agencies in order to manufacture and sell our products in the regions in which we operate. Obtaining this approval can be time consuming and costly. There can be no assurance that, in the event we submit an application for a marketing authorization to any global regulatory agency, we will obtain the approval to market a prescription or OTC product and/or that we will obtain it on a timely basis. Laws unique to the U.S. regulatory framework encourage generic competition by providing eligibility for first generic marketing exclusivity if certain conditions are met. If we are granted generic exclusivity, the exclusivity may be shared with other generic companies, including authorized generics; or it is possible that we may forfeit 180-day exclusivity if we do not obtain regulatory approval or begin marketing the product within the statutory requirements. Finally, if we are not the first to file our ANDA, the FDA may grant 180-day exclusivity to another company, thereby effectively delaying the launch of our product.

- Global regulatory agencies regularly inspect our manufacturing facilities and the facilities of our third-party suppliers. The failure of one of our facilities, or a facility of one of our third-party suppliers, to comply with applicable laws and regulations may lead to a breach of representations made to our customers, or to regulatory or government action against us related to the products made in that facility. Such action could include suspension of or delay in regulatory approvals. If the compliance violations are severe, agencies of the government may initiate product seizure, injunction, recall, suspension of production or distribution of our products, loss of certain licenses or other governmental penalties, or civil or criminal prosecution, thereby impacting the reputation of all of our products.

In the U.S., the DSCSA requires development of an electronic pedigree to track and trace each prescription drug at the salable unit level through the distribution system, which will be effective incrementally over a 10-year period beginning on January 1, 2015, for manufacturers, wholesale distributors, and re-packagers, and on July 1, 2015 for dispensers. Similarly, the European Commission passed legislation requiring new product packaging ‘safety features’ to prevent falsification of medicinal products primarily within the

prescription medicines sector. The act was adopted in October 2015 but has yet to be officially published. Marketing Authorization holders will have 3 years from the publication date to implement the necessary changes or risk forfeiting their product licenses. Compliance with the new U.S. and EU electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens.

- Global regulatory agencies highly scrutinize any product application submitted to switch a product from physician prescribed Rx to unsupervised OTC use by the general public.The expansion of Rx-to-OTC switches is critical to our future growth. Reluctance of regulatory agencies to approve Rx-to-OTC switches in new product categories could impact that growth.

- Several bills have been introduced in U.S. Congress that could, if enacted, affect the manufacture and marketing of Rx and OTC drugs including labeling and packaging. For example, the FDA is proposing to change existing regulations to permit generic drug application holders to revise their labeling without prior FDA review to add new safety information that may differ from the corresponding brand drug. The FDA announced that the Final Rule is targeted for publication by June 2016. If this proposed regulatory change is adopted, it may eliminate the preemption of certain failure-to-warn claims, with respect to generic drugs, which could have a material adverse impact on our future operating results. Regulatory bodies outside of the U.S. could enact similar legislation. We cannot predict whether further label restrictions may be required, or whether additional regulations in the U.S. or other countries in which we operate, may be passed.

- The regulatory agencies in the markets we serve may change the requirements for comparison or claim statements for our OTC products. Any labeling changes required for regulatory compliance could render our packaging inventories obsolete and could negatively impact future sales of the product.

- Our infant formula products may be subject to barriers or sanctions imposed by countries or international organizations limiting international trade and dictating the specific content of infant formula products. Governments could enhance regulations on the industry aimed at ensuring the safety and quality of dairy products, including, but not limited to, compulsory batch-by-batch inspection and testing for additional safety and quality issues. Such inspections and testing may increase our operating costs related to infant formula products.

- On June 10, 2014, the FDA published a final rule ("FR") entitled "Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula." The FR includes, among other things, new or modified requirements related to infant formula manufacturing, quality controls, record-keeping, and clinical trials. While it is uncertain how the FDA will interpret and enforce the FR, we are taking steps to comply with the provisions of the FR. Compliance with the FR could be costly. To the extent the FDA believes that we have not complied with the FR, we could experience potential supply chain disruptions and delays in commercialization of new infant formula products.

- We have expanded our pharmaceutical marketing to include direct interactions with healthcare professionals, which is known as “detailing.” This activity is subject to extensive regulation under a variety of U.S. laws and regulations, including anti-kickback, anti-bribery, and false claims laws; the FFDCA with respect to claims and off-label promotions; and similar laws in non-U.S. jurisdictions. If our marketing activities are found to be improper, we could be subject to civil and governmental actions and penalties. These risks may increase as non-U.S. jurisdictions adopt new anti-bribery laws and regulations.

- If we are unable to successfully obtain the necessary quota for controlled substances and List I chemicals, we risk having delayed product launches or failures to meet commercial supply obligations. If we are unable to comply with regulatory requirements for controlled substances and List I chemicals, the DEA, or similar regulatory agency, may

take regulatory actions, resulting in temporary or permanent interruption of distribution of our products, withdrawal of our products from the market, or other penalties.

- The Mexican Ministry of Health passed new laws requiring all marketing authorization holders to submit updated chemistry, manufacturing and controls information, and in some cases new mandatory bioequivalence studies, in the next license renewal. Failure to submit the required data would result in the

cancellation of the product license and loss of product marketing rights. Similar actions could be taken by other global regulatory agencies, which, if we failed to comply, could lead to commercial disruptions or possibly loss of marketing rights.

- The Israeli Ministry of Health has issued the first draft of a new Statement of Position ("SOP") that requires a Risk Management Plan ("RMP") to be submitted in all new product marketing authorizations. The SOP is based on European legislation and submission of the EU-approved RMP is preferred. Compliance with the new requirement will become effective beginning May 1, 2016. We are currently evaluating the new requirement and cannot predict how it will impact our future product launches and results of operations.

- Changes to the Medical Device Directive are anticipated in 2016, based on a proposal for new European Medical Device Regulation, which has been under discussion since 2012. These changes are expected to include increased supervision by the Notified Bodies by Competent Authorities and revisions to documentation requirements. We will monitor the regulation's progress and cannot currently predict how it will impact the future production and sale of products classified as medical devices.

- Our operations extend to numerous countries outside the U.S. and are subject to the risks inherent in conducting business globally and under the laws, regulations, and customs of various jurisdictions. These risks include compliance with a variety of national and local laws of countries in which we do business, such as restrictions on the import and export of certain intermediates, drugs, and technologies. We must also comply with a variety of U.S. laws related to doing business outside of the U.S., including Office of Foreign Asset Controls, United Nations and EU sanctions; the Iran Threat Reduction and Syria Human Rights Act of 2012; and rules relating to the use of certain “conflict minerals” under Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. Further changes in laws, regulations, and practices affecting the pharmaceutical industry and the healthcare system, including imports, exports, manufacturing, quality, cost, pricing, reimbursement, approval, inspection, and delivery of healthcare, may affect our business and operations.

Healthcare reform and related changes to reimbursement methods in and outside of the United States may have an adverse effect on our financial condition and results of operations.

Increasing healthcare expenditures have received considerable public attention in many of the countries in which we operate. In the U.S., government programs such as Medicare and Medicaid, as well as private insurers, have been focused on cost containment. In the EU and some other markets outside the U.S., the government provides healthcare at low direct cost to consumers and regulates pharmaceutical prices or patient reimbursement levels to control costs for the government-sponsored healthcare system. Both private and governmental entities are seeking ways to reduce or contain healthcare costs.

Our Rx segment in particular could be materially adversely impacted by measures taken by governmental entities or private insurers to restrict patients' access to our products or increase pressure on drug pricing, including denial of price increases, prospective and retrospective price decreases, and increased mandatory discounts or rebates. These actions may drive us and our competitors to decrease prices or may reduce the ability of customers to pay for our products, which could materially negatively impact the Rx segment's results of operations.

If we fail to comply with the reporting and payment obligations under the Medicaid rebate program or other governmental purchasing and rebate programs, we could be subject to fines or penalties, which could have an adverse effect on our financial condition and results of operations.

As described in Item 1. Business - Medicaid Drug Rebate Programs, we have a Medicaid rebate agreement and VA master agreement in effect with the U.S. government. There are inherent risks associated with participating in the Medicaid drug rebate program, and VA FSS program, including the following:

- We are required to report pricing data to CMS, including AMP, on a monthly and quarterly basis and BP and ASP on a quarterly basis. We also are required to report quarterly and annual Non-FAMPs to the VA. If we fail to submit required information, make misrepresentations, or knowingly submit false information to the government as to AMP, ASP, or BP, we may be liable for substantial civil monetary penalties or subject to other enforcement actions, such as under the False Claims Act, and CMS may terminate our Medicaid drug

rebate agreement. In that event, U.S. federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

- The Health Reform Law enacted in 2010 requires the use of AMP data to calculate FULs and amends the statutory definitions of AMP and "multiple source drug" in a manner that materially affects the calculation of FULs. CMS surveys and publishes retail community pharmacy acquisition cost information to provide state Medicaid agencies with a basis for comparing their own reimbursement and pricing methodologies and rates. On February 1, 2016, CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate program under the Health Reform Law. This regulation becomes effective on April 1, 2016. We are currently evaluating the impact of this regulation on our business and operations. Based on our initial evaluation we do not believe that the changes will have a material impact on our business. We do not know how the methodologies for calculating AMP and FULs or the retail survey acquisition cost information will affect our pharmacy customers or to what extent these customers will seek to pass on any decrease in Medicaid reimbursements to us. We also cannot predict how the sharing of FUL data and retail survey prices may impact competition in the marketplace.

- Statutory or regulatory changes or CMS binding guidance could affect the calculation of AMP, BP, or ASP for our products. Such changes could result in increases in our Medicaid rebate liability or reductions in the Medicare payment rate, and could negatively impact our results of operations.

- If we inadvertently overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we would be required to refund the difference. Failure to make necessary disclosures and/or to identify contract overcharges can result in False Claims Act allegations or potential violations of other laws and regulations. Unexpected refunds to the government, and responses to a government investigation or enforcement action, are expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

- Our reporting and payment obligations under the Medicaid rebate program and other governmental purchasing and rebate programs are complex and may involve subjective decisions. Our calculations and methodologies are subject to review by the governmental agencies, and it is possible that these reviews could result in challenges to our submissions. If we do not comply with those reporting and payment obligations, we could be subject to civil and/or criminal sanctions, including fines, penalties, and possible exclusion from U.S. federal healthcare programs (including Medicaid and Medicare).

We face vigorous competition from other pharmaceutical companies that may threaten the commercial acceptance and pricing of our products.

We operate in a highly competitive environment. Our products compete against store brand, generic, and branded pharmaceutical companies. Competition is also impacted by changes in regulations and government pricing programs that may give competitors an advantage.

- As a manufacturer of generic versions of brand-name drugs through our CHC and Rx segments, we experience competition from brand-name drug companies that may try to prevent, discourage or delay the use of generic versions through various measures, including introduction of new branded products, legislative initiatives, changing dosage forms or dosing regimens, regulatory processes, filing new patents or patent extensions, lawsuits, citizens' petitions, and negative publicity prior to introduction of a generic product. In addition, brand-name competitors may lower their prices to compete with generic products, increase advertising, or launch, either through an affiliate or licensing arrangements with another company, an authorized generic at or near the time the first generic product is launched, depriving the generic product market of the exclusivity intended by the Hatch-Waxman Act.

Our CHC and Rx segments also experience competition from our generic competitors, some of whom are significantly larger than we are, may develop their products more rapidly or complete regulatory approval processes sooner, or may market their products earlier than we do. If we are not the first to file our ANDA, the FDA may grant 180-day exclusivity to another company, which would prevent us from selling the

product during the exclusivity period. Even if we are the first to file, in certain circumstances, we may not be able to fully exploit our 180-day exclusivity period.

- Our CHC and Rx segments may experience increased price competition as other generic companies produce the same product, sometimes for dramatically lower margins in order to gain market share. Other generic companies may introduce new drugs and/or drug delivery techniques that make our current products less desirable. A drug may be subject to competition from alternative therapies during the period of patent protection or regulatory exclusivity, and thereafter we may be subject to further competition from generic products or biosimilars.

- The pharmaceutical industry is consolidating. This creates larger competitors and places further pressure on prices, development activities, and customer retention. Our animal health category within the CHC segment has seen a dramatic increase in direct to consumer advertising by several branded competitors, and our nutritionals category has experienced increased competition through alternative channels such as health food stores, direct mail, and direct sales.

- We develop and distribute branded products primarily through our BCH segment. We experience competition from other brand-name drug companies, many of which are larger and have more resources to devote to advertising and marketing. These direct competitors may be able to adapt more quickly to changes in customer requirements. Our current and future competitors may develop products comparable or superior to those offered by us at more competitive prices. If we are unable to compete successfully, our business will be harmed through loss of customers or increased negative pricing pressure that would adversely affect our ability to generate revenue and adversely affect our operating results.

- Lack of availability, or significant increases in the cost, of raw materials used in manufacturing our products could adversely impact our profit margins and operating results.

Affordable high quality raw materials and packaging components are essential to all of our business units due to the nature of the products we manufacture. In addition, maintaining good supply relationships is essential to our ongoing operations. See Item 1. Business - Materials Sourcing for more information.

- We maintain several single-source supplier relationships, either because alternative sources are not available or because the relationship is advantageous due to regulatory, performance, quality, support, or price considerations. Unavailability or delivery delays of single-source components or products could adversely affect our ability to ship the related product in a timely manner. The effect of unavailability or delivery delays would be more severe if associated with our higher-volume or more profitable products. Even where alternative sources of supply are available, qualifying the alternate suppliers and establishing reliable supplies could cost more or result in delays and a loss of net sales. Additionally, global regulatory requirements for obtaining product approvals could substantially lengthen the approval of an alternate material source. As a result, the loss of a single-source supplier could have a material adverse effect on our results of operations.

- The rapid increase in cost of many raw materials from inflationary forces, such as increased energy costs, and our ability or inability to pass on these increases to our customers could have a negative material impact on our financial results.

- Our infant formula products require certain key raw ingredients that are derived from raw milk, such as skim milk powder, whey protein powder, and lactose. Our supply of milk-based ingredients may be limited by the ability of individual dairy farmers and cooperatives to provide raw milk in the amount and quality we deem necessary. Raw milk production is influenced by factors beyond our control including seasonal and environmental factors,

governmental agricultural and environmental policy, and global demand. We cannot guarantee that there will be sufficient supplies of these key ingredients necessary to produce infant formula.

Our products, and the raw materials used to make those products, generally have limited shelf lives. Our inventory levels are based, in part, on expectations regarding future sales. We may experience build-ups in inventory if sales slow. Any significant shortfall in sales may result in higher inventory levels of raw materials and finished products, thereby increasing the risk of inventory spoilage and corresponding inventory write-

downs and write-offs. Cargo thefts and/or diversions, and economically or maliciously motivated product tampering on store shelves may occur, causing unexpected shortages, which may have a material impact on our operations.

- We rely on third parties to source many of our raw materials, as well as to manufacture sterile, injectable products that we distribute. We maintain a strict program of verification and product testing throughout the ingredient sourcing and manufacturing process to identify potential 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 and lost revenue, harm our reputation, and may give rise to product liability litigation.

- Changes in regulation could impact the supply of API and certain other raw materials used in our products. For example, the EU recently promulgated new standards requiring all API imported into the EU be certified as complying with GMP established by the EU. The regulations placed the certification requirement on the regulatory bodies of the exporting countries, which led to an API supply shortage in Europe as certain governments were not willing or able to comply with the regulation in a timely fashion, or at all. A shortage in API or other raw ingredients could cause us to have to cease manufacture of certain products, or to incur costs and delays to qualify other suppliers to substitute for those API manufacturers are unable to export. This could have a material adverse effect on our business, results of operations, financial condition, and cash flow.

A disruption at any of our main manufacturing facilities could materially and adversely affect our business, financial position, and results of operations.

Our manufacturing operations are concentrated in a few locations. See Item 1. Business - Manufacturing and Distribution for more information on our significant operations. A significant disruption at one or more of these facilities, whether it be due to fire, natural disaster, power loss, intentional acts of vandalism, war, terrorism, insufficient quality, or pandemic could materially and adversely affect our business.

Additionally, regulatory authorities routinely inspect all of our manufacturing facilities for cGMP compliance. While our manufacturing sites are cGMP compliant, if a regulatory authority were to identify serious adverse findings not corrected upon follow up inspections, we may be required to issue product recalls, shutdown manufacturing facilities, and take other remedial actions. If any manufacturing facility were forced to cease or limit production, our business could be adversely affected.

Any breach or disruption of our information systems could have a material adverse effect on our business.

Our systems, information, and operations, as well as our independent vendor relationships (where they support information technology and manufacturing infrastructure), are highly complex and vulnerable to disruption or damage from security breaches, hacking, data theft, denial of service attacks, human error, sabotage, industrial espionage, and computer viruses. Such events may be difficult to detect; and, once detected, their impact may be difficult to assess. While we continue to employ resources to monitor our systems and protect our infrastructure, these measures may prove insufficient depending upon the attack or threat posed. These risks include:

- Breaches or disruptions could impair our ability to develop, meet regulatory approval efforts for, produce, and/or ship products, take and fulfill orders, and/or collect and make payments on a timely basis;
- Any system issue, whether as a result of an intentional breach or a natural disaster, could damage our reputation and cause us to lose customers, experience lower sales volume, and incur significant liabilities; and
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We could incur significant expense in addressing a disruption and in addressing related data security and privacy concerns.

Perrigo Company plc - Item 1A
Risk Factors

Because our business depends upon certain customers for a significant portion of our sales, our business would be adversely affected by a disruption of our relationship with these customers or any material adverse change in these customers' businesses.

Sales to our largest customer, Walmart, comprised approximately 13% of our total net sales for the six months ended December 31, 2015. While no other customer individually comprised more than 10% of total net sales, we do have other significant customers. If our relationship with one or more of these other customers, including the terms of doing business with the customers, changes significantly, it could have a material adverse impact on us. See Item 1. Business - Significant Customers for more information.

Many of our customers, which include chain drug stores, wholesalers, distributors, hospital systems, and group purchasing organizations, continue to merge or consolidate. Such consolidation has provided, and may continue to provide, customers with additional purchasing leverage, and consequently may increase the pricing pressures we face. The emergence of large buying groups representing independent retail pharmacies enable those groups to extract price discounts on our products. In addition, a number of our customers have instituted sourcing programs limiting the number of suppliers of generic pharmaceutical products carried by that customer. These developments have resulted in heightened pricing pressure on our products, as well as competition among generic drug producers for business from a smaller and more selective customer base.

Additionally, if we are unable to maintain adequately high levels of customer service over time, customers may choose to assess penalties, obtain alternate sources for products, and/or end their relationships with us.

Our Specialty Sciences segment generates revenue primarily from royalties on Tysabri®, and any negative developments related to Tysabri® could have a material adverse effect on our business.

We occasionally enter into arrangements that entitle us to potential royalties from third parties. Our most significant royalty is the Tysabri® royalty received quarterly from Biogen, which generated $167.3 million of pretax income during the six months ended December 31, 2015. See Item 1. Business - Specialty Sciences for more information on our Tysabri® royalty arrangement. Our pretax income could be adversely affected if the royalty streams decline in future periods. Factors that may have an adverse effect on our Tysabri® royalty stream include:

- Foreign currency movement, which could have a negative impact on Biogen's Tysabri® sales, thereby reducing our royalties;
- Companies working to develop new therapies or alternative formulations of products for multiple sclerosis that, if successfully developed, would compete with, or could gain greater acceptance than, Tysabri® and damage our market share;
- Any negative developments relating to Tysabri®, such as safety, efficacy, or reimbursement issues, could reduce demand for Tysabri®; and
- Adverse regulatory or legislative developments could limit or prohibit the sale of Tysabri®, such as restrictions on the use of Tysabri® or safety-related label changes, including enhanced risk management programs, which may significantly reduce expected net sales and require significant expense and management time to address the associated legal and regulatory issues.

Additionally, Tysabri® sales growth cannot be assured given the significant restrictions on its use and the significant safety warnings on the label, including the risk of developing Progressive Multifocal Leukoencephalopathy ("PML"),

a serious brain infection. The risk of developing PML may increase with prior immunosuppressant use, longer treatment duration, or the presence of certain antibodies. Increased incidence of PML could limit sales growth, prompt regulatory review, require significant changes to the label, or result in market withdrawal. In addition, the result of ongoing or future clinical trials involving Tysabri® or other adverse events reported in association with the use of Tysabri® may have an adverse impact on prescribing behavior and reduce sales of Tysabri®.

Perrigo Company plc - Item 1A
Risk Factors

We are dependent on the services of certain key executive and scientific employees. The failure to attract and retain such employees may have a material adverse impact on our results of operations.

We are dependent on the services of certain key employees, and our future success will depend in large part upon our ability to attract and retain highly skilled employees. In particular, key employees of acquired companies may perceive uncertainty about their future role until strategies regarding the combined business are fully executed. Key functions for us include executive managers, operational managers, R&D scientists, information technology specialists, financial and legal specialists, regulatory professionals, quality compliance specialists, and sales/marketing personnel. If we are unable to attract or retain key qualified employees, our future operating results may be adversely impacted.

Unfavorable publicity or consumer perception of the safety, quality, and efficacy of our products could have a material adverse impact on our business.

We are dependent upon consumers' perception of the safety, quality, and efficacy of our products, and may be affected by changing consumer preferences. Negative consumer perception may arise from media reports, product liability claims, regulatory investigations, or recalls, regardless of whether they involve us or our products. The mere publication of information asserting defects in products or ingredients, or concerns about our products or the materials used in our products, could discourage consumers from buying our products, regardless of whether such information is scientifically supported.

- Our products involve risks such as product contamination, spoilage, mislabeling, and tampering that could require us to recall one or more of our products. Serious product quality concerns could also result in governmental actions against us that, among other things, could result in the suspension of production or distribution of our products, product seizures, loss of certain licenses, delays in the issuance of governmental approvals for new products, or other governmental penalties, all of which could be detrimental to our reputation and reduce demand for our products.

- We cannot guarantee that counterfeiting, imitation or other tampering with our products will not occur or that we will be able to detect and resolve it. Any counterfeiting or contamination of any products could negatively impact our reputation and sales, particularly if counterfeit or imitation products cause death or injury to consumers.

- Many of the brands we acquired from Omega have European recognition. This recognition is the result of the large investments Omega has made in its products over many years. The quality and safety of the products are critical to our business. If we are unable to effectively manage real or perceived issues, including concerns about safety, quality, efficacy, or similar matters, sentiments toward us and our products could be negatively impacted.

- Our BCH segment's financial success is dependent on the success of its brands, and the success of these brands can suffer if marketing plans or product initiatives do not have the desired impact on a brand’s image or its ability to attract consumers and the performance of the segment may be negatively impacted if spending on such plans and initiatives does not generate the returns we anticipate. In addition, given the association of individual products within the commercial network of our BCH segment, an issue with one of our products could negatively affect the reputation of other products, thereby potentially hurting our financial results.

- Powdered infant formula products are not sterile. All of our infant formula products must be prepared and maintained according to label instruction to retain their flavor and nutritional value and avoid contamination or deterioration. Depending on the product, a risk of contamination or deterioration may exist at each stage of the production cycle, including the purchase and delivery of raw materials, the processing and packaging of food products, and the use and handling by consumers, hospital personnel, and healthcare professionals. In the event that certain of our infant

formula products are found or alleged to have suffered contamination or deterioration, whether or not under our control, our reputation and our infant formula product category sales could be materially adversely affected.

Perrigo Company plc - Item 1A
Risk Factors

- Scientific studies and media reports can have a negative impact on the demand for certain of our products, regardless of whether they directly involve us. For instance, there have been recent reports and investigations questioning the efficacy of regular consumption of certain vitamins and supplements and challenging the dietary supplement industry. Our VMS sales have been negatively impacted by the media attention.

Increasing use of social media could give rise to liability, breaches of data security, or reputation damage.

The Company and our employees increasingly utilize social media as a means of internal and external communication.

- To the extent that we seek to use social media tools as a means to communicate about our products and/or business, there are uncertainties as to the rules that apply to such communications, or as to the interpretations that authorities will apply to the rules that exist. As a result, despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that our use of social media for such purposes may cause us to be found in violation of them. A violation of such guidelines may damage our reputation as well as cause potential lawsuits and adversely affect our operating activities.

- Our employees may knowingly or inadvertently make use of social media tools in ways that may not be aligned with our social media strategy, may give rise to liability, or could lead to the loss of trade secrets or other intellectual property, or public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others.

- Negative posts or comments about us, store brands or generic pharmaceuticals, or our products in social media could seriously damage our reputation and could adversely affect the price of our securities. In addition, negative posts or comments about our products could result in increased pharmacovigilance reporting requirements, which may give rise to liability if we fail to fully comply with such requirements.

Our quarterly results are impacted by a number of factors, some of which are beyond the control of our management, that may result in significant quarter-to-quarter fluctuations in operating results.

Our quarterly results are impacted by a number of factors, some of which are beyond the control of management, that may result in significant quarter-to-quarter fluctuations in operating results. Some of these factors include the severity, length and timing of the cough/cold/flu and allergy season, and flea and tick season, the timing of new product approvals and introductions by us and our competitors, price competition, changes in the regulatory environment, changes in accounting pronouncements, the magnitude and timing of R&D investments, changes in the levels of inventories maintained by our customers, and the timing of retailer promotional programs.

We may not realize the benefits of business acquisitions and divestitures we enter into, which could have a material adverse effect on our operating results.

One of our strategies is inorganic growth through the acquisition of products and companies that we expect will benefit the Company. This strategy comes with a number of financial, managerial, and operational risks. We may not realize the benefits of an acquisition because of integration and other challenges, including, but not limited to the following:

- The difficulty involved with managing the expanded operations of a larger and more complex company;

- Uncertainties involved in assessing the value, strengths, and potential profitability of, and identifying the extent of all weaknesses, risks, and contingent and other liabilities of the respective parties;

- Unanticipated changes in the business, industry, market or general economic conditions different from the assumptions underlying our rationale for pursuing the transaction;

- Potential inability to achieve identified operating and financial synergies, or return on investment, from an acquisition in the amounts or on the time frame anticipated;

- Substantial demands on our management, operational resources, technology, and financial and internal control systems, which could lead to dissatisfaction and potential loss of key customers, management, or employees;

- Integration activities may detract attention from our day-to-day business, and there might be substantial costs associated with the transaction process or other material adverse effects as a result of these integration efforts; and

- We may undertake financing to complete an acquisition that impacts our liquidity, credit ratings and financial position, thereby making it more difficult, restrictive or expensive to raise future capital.

Actual results may differ from pro forma financial information of the combined companies due to changes in the fair value of assets acquired and liabilities assumed, changes in assumptions used to form estimates, differences in accounting policies between the companies, and completion of purchase accounting. In addition, we may enter into new product or geographical markets which are unknown to us and which may be difficult to properly manage.

On March 30, 2015, we completed the acquisition of Omega, which now comprises our BCH segment. Subsequent to acquiring Omega, we acquired several products (GSK products and Yokebe®), which were added to the BCH segment. The BCH segment operates in 36 countries and accordingly may experience changes in performance based on specific strategies, market dynamics, product marketing plans, or other factors related to each respective market. Further, each country has processes in place to manage advertising and promotion, inventory fulfillment, and commercial agreements with customers in those markets relating to pricing, product returns, credit terms, and other commercial requirements. Accordingly, performance in each respective market is subject to these agreements and practices.

The net sales and operating income of our BCH segment were lower than our expectations during the three months ended December 31, 2015. Excluding the impact of acquisitions, net sales were lower than Omega's prior year primarily in three main markets: Belgium, Spain, and Germany. Belgium includes the segment's generic distributions business, which experienced lower sales during the six months ended December 31, 2015. Excluding the impact of recently completed acquisitions, net sales in Spain and Germany were considerably below Omega's prior year net sales and our expectations during the three months ended December 31, 2015 due to lower sales of lifestyle and VMS products. Further, the BCH segment's operating income was lower than our expectations due primarily to the change in sales in these markets, issues with sales and inventory forecasting and management procedures, costs associated with excess inventory, product returns, and advertising and promotion initiatives incurred during the three months ended December 31, 2015. We are in the process of implementing sales forecasting, inventory planning and control procedures, and financial planning and analysis systems in the segment consistent with Perrigo practices.

There can be no assurance that we will not continue to experience challenges related to the BCH segment and these challenges could have a material impact on our business, cash flows, and results of operations.

We have acquired significant assets that could become impaired or subject us to losses and may result in an adverse impact on our results of operations.

We have recorded significant intangible assets and goodwill on our balance sheet as a result of previous acquisitions, which could become impaired and lead to material charges in the future. We regularly review our intangible assets and goodwill for impairment. Goodwill and indefinite life intangible assets are subject to impairment review on an annual basis and whenever impairment indicators are present.

For the six months ended December 31, 2015, we recorded an impairment of certain indefinite-lived intangible assets based on management's expectations of the prospects for future revenues, profits, and cash flows associated with these assets. The indefinite-lived intangible assets were purchased in conjunction with the Omega acquisition and are included in the BCH segment. The assessment utilized the excess earnings method to determine fair value and resulted in an impairment charge of $185.1 million. This impairment represented the

difference between the carrying amount of the intangible assets and their estimated fair value. See Item 8. Note 3 for further information.

No goodwill impairment charges were recorded for the six months ended December 31, 2015, however our testing indicated that our Specialty Sciences reporting unit's fair value exceeded its carrying value by less than 10%. Management evaluated the primary source of cash flow in this segment, the Tysabri® royalty stream, based on a combination of factors including independent external research, information provided from our royalty partner, and internal estimates. Based on this information, management's expectations for future cash flow from this royalty stream have been reduced primarily due to anticipated new competitors entering the market and unfavorable changes in the U.S. dollar relative to other currencies. Actual performance different from the assumptions utilized in our quantitative analysis may further reduce the fair value of the reporting unit, which may result in the fair value no longer exceeding the carrying value, which would require us to record an impairment charge.

We perform an impairment analysis on intangible assets subject to amortization when there is an indication that the carrying amount of any individual asset may not be recoverable. Any significant change in market conditions, estimates or judgments used to determine expected future cash flows that indicates a reduction in carrying value may give rise to impairment in the period that the change becomes known.

There can be no assurance that our strategic initiatives will achieve their intended effects.
We are in the process of implementing certain initiatives designed to increase operational efficiency and improve our return on invested capital by globalizing our supply chain through global shared service arrangements, streamlining our organizational structure, and disposing of certain assets. We believe these initiatives will enhance our revenue, operating margins, and earnings; however, there can be no assurance that these initiatives will produce the anticipated benefits. Any delay or failure to achieve the anticipated benefits could have a material adverse effect on our projected results.

Global Risks

Our business, financial condition, and results of operations are subject to risks arising from the international scope of our operations.

We manufacture, source raw materials, and sell our products in a number of countries. The percentage of our business outside the U.S. has been increasing. We are subject to risks associated with international manufacturing and sales, including:

- Unexpected changes in regulatory requirements;
- Problems related to markets with different cultural biases or political systems;
- Possible difficulties in enforcing agreements;
- Longer payment cycles and shipping lead-times;
- Difficulties obtaining export or import licenses or changes in import/export regulations; and
- Imposition of withholding or other taxes.

Additionally, we are subject to periodic reviews and audits by governmental authorities responsible for administering import/export regulations. To the extent that we are unable to successfully defend against an audit or review, we may be required to pay assessments, penalties, and increased duties.

Certain of our facilities operate in a special purpose sub-zone established by the U.S. Department of Commerce Foreign Trade Zone Board, which allows us certain tax advantages on products and raw materials shipped through

these facilities. If the Foreign Trade Zone Board were to revoke the sub-zone designation or limit our use, we could be subject to increased duties.

Although we believe that we conduct our business in compliance with applicable anti-corruption, anti-bribery and economic sanctions or other anti-corruption laws, if we are found to not be in compliance with such laws or other anti-corruption laws, we could be subject to governmental investigations, legal or regulatory proceedings, substantial fines, and/or other legal or equitable penalties. This risk increases in locations outside of the U.S., particularly in locations that have not previously had to comply with the FCPA, U.K. Bribery Act, and similar laws.

Perrigo Company plc - Item 1A
Risk Factors

Current and changing global economic conditions may adversely affect our business.

A number of non-U.S. jurisdictions in which we do business have been negatively impacted by slowing growth rates or recessionary conditions and market volatility.

- Several emerging market economies are particularly vulnerable to the impact of rising interest rates, inflationary pressures, weaker oil and other commodity prices, and large external deficits. While some of these jurisdictions are showing signs of stabilization or recovery, others, such as Ukraine, Russia and Greece, continue to experience increasing levels of stress and volatility. Risks in one country can limit our opportunities for portfolio growth and negatively affect our operations in another country or countries. As a result, any such unfavorable conditions or developments could have an adverse impact on our operations.

- While the challenging global economic environment has not had a material impact on our liquidity or capital resources, there can be no assurance that possible future changes in global financial markets and global economic conditions will not affect our liquidity or capital resources, impact our ability to obtain financing in the future, or decrease the value of our assets.

- Our customers could be adversely impacted if economic conditions worsen. Our CHC segment does not advertise its products like national brand companies and thus is largely dependent on retailer promotional activities to drive sales volume and increase market share. If our customers do not have the ability to invest in store brand promotional activities, our sales may suffer. Additionally, while we actively review the credit worthiness of our customers and suppliers, we cannot fully predict to what extent they may be negatively impacted by slowing economic growth.

The international scope of our business exposes us to risks associated with foreign exchange rates.

We report our financial results in U.S. dollars. However, a significant portion of our net sales, assets, indebtedness and other liabilities, and costs are denominated in foreign currencies. These currencies include among others the euro, Indian rupee, British pound, Canadian dollar, Israeli shekel, Australian dollar, and Mexican peso. The addition of Omega, a euro-denominated business, that represents a significant portion of our net sales and earnings, and a substantial portion of our net assets, has significantly increased our exposure to changes in the euro/U.S. dollar exchange rate. In addition, approximately 25% of Omega’s sales are in other foreign currencies, with the majority of the product costs for these markets denominated in euros. Our results of operations and, in some cases, cash flows, have in the past been, and may in the future, be adversely affected by movements in exchange rates. In addition, we may also be exposed to credit risks in some of those markets. We may implement currency hedges or take other actions intended to reduce our exposure to changes in foreign currency exchange rates. If we are not successful in mitigating the effects of changes in exchange rates on our business, any such changes could materially impact our results.

We operate in jurisdictions that could be affected by economic and political instability, which could have a material adverse effect on our business.

Our operations outside the U.S. could be affected by economic or political instability, embargoes, military hostilities, unstable governments and legal systems, and inter-governmental disputes. We have significant operations in Israel, which has experienced varying degrees of hostility in recent years. Doing business in Israel and certain other regions including Mexico and Eastern Europe involves the following risks:

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Certain countries and international organizations have refused to do business with companies with Israeli operations. We are also precluded from marketing our products to certain countries due to U.S. and Israeli regulatory restrictions. International economic sanctions and boycotts of our products could negatively impact our sales and ability to export our products.

Perrigo Company plc - Item 1A
Risk Factors

- Our facilities in Israel are within a conflict zone. If terrorist acts or military actions were to result in substantial damage to our facilities, our business activities would be disrupted since, with respect to most products, we would need to obtain prior regulatory agency approval for a change in manufacturing site. In addition, our insurance may not adequately compensate us for losses that may occur, and any losses or damages incurred by us could have a material adverse effect on our business.
- The U.S. Department of State and other governments have at times issued advisories regarding travel to certain countries in which we do business. As a result, regulatory agencies have at various times curtailed or prohibited their inspectors from traveling to inspect facilities. If these inspectors are unable to inspect our facilities, the regulatory agencies could withhold approval for new products intended to be produced at those facilities.

- Our international operations may be subject to interruption due to travel restrictions, war, terrorist acts, and other armed conflicts. For example, Belgium and Eastern Europe may be exposed to further acts of terrorism, which could give rise to travel and increased security restrictions. Also, further threats of armed hostilities in Mexico could limit or disrupt markets and our operations, including disruptions resulting from the cancellation of contracts or the loss of assets. These events could have a material adverse effect on our international business operations.

Risks Related to Litigation and Insurance

- We are or may become involved in lawsuits and may experience unfavorable outcomes of such proceedings.

We may become involved in lawsuits arising from various commercial matters, including, but not limited to, competitive issues, contract issues, intellectual property matters, false advertising/unfair competition, taxation matters, workers' compensation, product quality/recall issues, environmental remediation issues, and regulatory issues. Litigation is unpredictable and can be costly. No assurance can be made that litigation will not have a material adverse effect on our financial position or results of operations in the future. See Item 8. Note 16 for more information.

- We may be subject to liability if our products violate applicable laws or regulations in the jurisdictions where our products are distributed. The successful assertion of product liability or other product-related claims against us could result in potentially significant monetary damages, and we could incur substantial legal expenses. Even if a product liability or consumer fraud claim is unsuccessful, not merited, or not fully pursued, we may still incur substantial legal expenses defending against such a claim, and our reputation may suffer.

- We are a defendant in product liability lawsuits arising out of serious adverse events, including deaths, which occurred in patients taking Tysabri®. We expect additional product liability lawsuits related to Tysabri® usage to be filed. Tysabri®'s distributor, Biogen, and Perrigo will each be responsible for 50% of losses and expenses arising out of any Tysabri® product liability claims. Along with Biogen, we intend to vigorously defend these lawsuits, however, we cannot predict how these cases will be resolved. Adverse results in one or more of these cases could result in substantial monetary judgments not covered by insurance.

- We may face environmental exposures including, for example, those relating to discharges from and materials handled as part of our operations, the remediation of soil and groundwater contaminated by hazardous substances or wastes, and the health and safety of our employees. While we do not have any material remediation liabilities currently outstanding, we 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 our currently or formerly owned property, or from a third-party disposal facility that we may have used, without regard to whether we knew of, or caused, the presence of the contaminants. The actual or alleged presence of these substances, or the failure to remediate them, could have adverse effects, including, for example, substantial investigative or remedial obligations and limitations on our 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 us. See Item 1. Business - Information Applicable to All Reportable Segments - Environmental for more information.

- Our BCH segment regularly makes advertising claims regarding the effectiveness of its products, which we are responsible for defending. An unsuccessful defense of product-related claims could result in potentially significant monetary damages and substantial legal expenses. Even if a claim is unsuccessful, not merited, or not fully pursued, we may still incur substantial legal expenses defending against such a claim, and our reputation could suffer.

Third-party patents and other intellectual property rights may limit our ability to bring new products to market and may subject us to potential legal liability, causing us to incur significant costs.

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.

- As a manufacturer of generic pharmaceutical products, the ability of our CHC and Rx segments to bring new products to market is often limited by third-party patents or proprietary rights and regulatory exclusivity periods awarded on products. Launching new products prior to resolution of intellectual property issues may result in us incurring legal liability if the related litigation is later resolved against us. The cost and time for us to develop prescription and Rx-to-OTC switch products is significantly greater than the rest of the new products that we introduce. Any failure to bring new products to market in a timely manner could cause us to lose market share, and our operating results could suffer.

- We could have to defend against charges that we violated patents or proprietary rights of third parties. This could require us to incur substantial expense and could divert significant effort of our technical and management personnel. If we are found to have infringed on the rights of others, we could lose our right to develop or manufacture some products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. Additionally, if we choose to settle a dispute through licensing or similar arrangements, the costs associated with these arrangements may be substantial and could include ongoing royalties. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling a number of our products.
- At times, our CHC or Rx segments may seek approval to market NDA or ANDA products before the expiration of patents for those products, based upon our belief that such patents are invalid, unenforceable or would not be infringed by our products. In these cases we may face significant patent litigation. Depending upon a complex analysis of a variety of legal and commercial factors, we 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, known 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 the patent holder may include, among other things, damages measured by the profits lost by the holder, which are often significantly higher than the profits we make from selling the generic version of the product. By electing to proceed in this manner, we could face substantial damages if we receive an adverse final court decision. In the case where a patent holder is able to prove that our infringement was "willful" or "exceptional," under applicable law, the patent holder may be awarded up to three times the amount of its actual damages or we may be required to pay attorneys' fees.

The success of certain of our products depends on the effectiveness of measures we take to protect our intellectual property rights and patents.

If we fail to adequately protect our intellectual property, competitors may manufacture and market similar products.

- We have been issued patents covering certain of our products, and we have filed, and expect to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the U.S. Any existing or future patents issued to or licensed by us may not provide us with any significant competitive

advantages for our products or may even be challenged, invalidated, or circumvented by competitors. In addition, patent rights may not prevent our competitors from developing, using, or commercializing non-infringing products that are similar or functionally equivalent to our products.

Perrigo Company plc - Item 1A
Risk Factors

- We also rely on trade secrets, unpatented proprietary know-how, and continuing technological innovation that we seek to protect, in part by confidentiality agreements with licensees, suppliers, employees, and consultants. If these agreements are breached, we 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, we may not be able to maintain the value of such intellectual property rights.

Significant increases in the cost or decreases in the availability of the insurance we maintain could adversely impact our financial condition.

To protect the Company against various potential liabilities, we maintain a variety of insurance programs, including property, general and product, and directors' and officers' liability. We may reevaluate and change the types and levels of insurance coverage that we purchase. We are self-insured when insurance is not available or not available at reasonable premiums. Risks associated with insurance plans include:

- Insurance costs could increase significantly, or the availability of insurance may decrease, either of which could adversely impact our financial condition;
- Deductible or retention amounts could increase or our coverage could be reduced in the future and to the extent losses occur, there could be an adverse effect on our financial results depending on the nature of the loss and the level of insurance coverage we maintained;
- Product liability insurance may not be available to us at an economically reasonable cost (or at all for certain specific products) or our insurance may not adequately cover our liability in connection with product liability claims (see Item 8. Note 16 for further information related to legal proceedings); and
- As our business inherently exposes us to claims for injuries allegedly resulting from the use of our products, we may become subject to claims for which we are not adequately insured. Unanticipated payment of a large claim may have a material adverse effect on our business.

Tax Related Risks

The U.S. Internal Revenue Service ("IRS") may not agree with the conclusion that we are treated as a foreign corporation for U.S. federal tax purposes.

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to section 7874 of the U.S. Internal Revenue Code of 1986, as amended ("Code"). For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because we are an Irish incorporated entity, we would generally be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules.

Section 7874 of the Code provides an exception under which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes.

For Perrigo Company plc to be treated as a foreign corporation for U.S. federal tax purposes under section 7874 of the Code, either (i) the former stockholders of Perrigo Company must own (within the meaning of section 7874 of the Code) less than 80% (by both vote and value) of our stock by reason of holding shares in Perrigo Company (the "ownership test") as of the closing of the Elan acquisition or (ii) we must have substantial business activities in Ireland after the Elan acquisition (taking into account the activities of our expanded affiliated group).

Upon our acquisition of Elan, Perrigo Company stockholders held 71% (by both vote and value) of our shares. As a result, we believe that under current law, we should be treated as a foreign corporation for U.S. federal tax purposes. However, we cannot assure that the IRS will agree with our position that the ownership test is satisfied. There is limited guidance regarding the section 7874 provisions, including the application of the ownership test.

Based on the limited guidance available, we currently expect that Section 7874 of the Code likely will limit our and our U.S. affiliates' ability to use their U.S. tax attributes such as net operating losses to offset certain U.S.

taxable income, if any, generated by the Elan acquisition or certain specified transactions for a period of time following the Elan acquisition.

Changes to tax laws could have a material adverse effect on our results of operations and the ability to utilize cash in a tax efficient manner.

We believe that under current law, we should be treated as a foreign corporation for U.S. federal tax purposes. However, any of the following could adversely affect our status as a foreign corporation for U.S. federal tax purposes:

- Changes to the inversion rules in section 7874 of the Code, the IRS Treasury regulations promulgated thereunder, or other IRS guidance; and
- Legislative proposals aimed at expanding the scope of U.S. corporate tax residence.

For example, the Department of the Treasury and the IRS provided notice in September 2014 and November 2015 that the agencies intend to issue regulations to reduce the tax benefits of or preclude entirely certain inversion transactions. In the November 2015 notice, the Secretary of the Treasury communicated the intention to explore potential guidance on earnings stripping and take further action in the coming months.

The Office of the Revenue Commissioners, U.S. Congress, the Organization for Economic Co-operation and Development ("OECD"), and other Government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations. One example is in the area of "base erosion and profit shifting" ("BEPS"), where taxpayers arbitrage between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates or structure their transfer pricing arrangements to minimize tax. The OECD published fifteen action item reports and recommendations last fall, and the EU has made current proposals to enact the recommendations. Although U.S. tax officials generally state that BEPS will not require changes in U.S. law, it could affect U.S. tax regulations, and the regulations of other countries in which we and our affiliates do business.

Any of these changes could have a prospective or retroactive application to us, our shareholders, and affiliates, and could adversely affect us by limiting our ability to utilize cash in a tax efficient manner.

Our effective tax rate may change in the future, which could adversely impact our future results from operations.

A number of factors may adversely impact our future effective tax rates, which may impact our future results from operations. These factors include, but are not limited to:

- Income tax rate changes by governments;
- The jurisdictions in which our profits are determined to be earned and taxed;
- Changes in the valuation of our deferred tax assets and liabilities;
- Adjustments to estimated taxes upon finalization of various tax returns;
- Adjustments to our interpretation of transfer pricing standards, changes in available tax credits, grants and other incentives;
-

Changes in stock-based compensation expense; changes in tax laws or the interpretation of such tax laws (such as proposals for fundamental U.S. international tax reform);

- Changes in U.S. generally accepted accounting principles;
- Expiration or the inability to renew tax rulings or tax holiday incentives; and
- Repatriation of non-U.S. earnings with respect to which we have not previously provided for U.S. taxes.

The resolution of uncertain tax positions could be unfavorable, which could have an adverse effect on our business.

Although we believe that our tax estimates are reasonable and that our tax filings are prepared in accordance with all applicable tax laws, the final determination with respect to any tax audit, and any related litigation, could be materially different from our estimates or from our historical income tax provisions and accruals. The results of an audit or litigation could have a material effect on operating results or cash flows in the periods for which that determination is made. In addition, future period earnings may be adversely impacted by litigation costs, settlements, penalties or interest assessments.

- The IRS audit of our fiscal years ended June 27, 2009 and June 26, 2010 had previously concluded with the issuance of a statutory notice of deficiency on August 27, 2014. While we had previously agreed on certain adjustments and made associated payments of $8.0 million inclusive of interest in November 2014, the statutory notice of deficiency asserted various additional positions, including transfer pricing, relative to the audit of fiscal years ended June 27, 2009 and June 26, 2010. The statutory notice asserted an incremental tax obligation of approximately $68.9 million, inclusive of interest and penalties. We disagree with the IRS's positions asserted in the notice of deficiency. In January 2015, we paid this amount, a prerequisite to being able to contest the IRS's positions in U.S. Federal court, and in June 2015 we filed a request for a refund. The IRS denied our request for a refund. In the next several months we are likely to file a complaint in federal district court claiming a refund for these amounts. An unfavorable resolution of this matter could have a material impact on our consolidated financial statements in future periods.

- The IRS is auditing our fiscal years ended June 25, 2011 and June 30, 2012, and may make adjustments consistent with their claims for the fiscal years ended June 27, 2009 and June 26, 2010. Subsequent to December 31, 2015, the Belgium Tax Authority notified us that all Belgium locations will be audited for the years ending December 31, 2013 and December 31, 2014.

There are numerous other income tax jurisdictions for which tax returns are not yet settled, none of which are individually significant. At this time, we cannot predict the outcome of any audit or related litigation.

Risks Related to Capital and Liquidity

Our indebtedness could adversely affect our ability to operate our business.

We anticipate that cash, cash equivalents, cash flows from operations, and borrowings available under our credit facilities will substantially fund working capital and capital expenditures. Our business requires continuous capital investments, and there can be no assurance that financial capital will always be available on favorable terms or at all. Additionally, our leverage and debt service obligations could adversely affect the business. At December 31, 2015, our total indebtedness outstanding was $6.0 billion.

- Downgrades to our credit ratings may limit our access to capital and materially increase borrowing costs on current or future financing, including via trade payables with vendors. Customers' inclination to purchase goods from us may also be affected by the publicity associated with deterioration of our credit ratings.

- Our senior credit facilities, the agreements governing our senior notes, and agreements governing our other indebtedness contain a number of restrictions and covenants that limit our ability to make distributions or other payments to our investors and creditors unless certain financial tests or other criteria are satisfied.

We also must comply with certain specified financial ratios and tests. These restrictions could affect our ability to operate our business and may limit our ability to take advantage of potential business opportunities, such as acquisitions. If we do not comply with the covenants and restrictions contained in our senior credit facilities, agreements governing our senior notes, and agreements governing our other indebtedness, we could be in default under those agreements, and the debt, together with accrued interest, could then be declared immediately due and payable.

Perrigo Company plc - Item 1A
Risk Factors

- Any default under our senior credit facilities or agreements governing our 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 our indebtedness is accelerated, there can be no assurance that we would be able to repay or refinance our debt or obtain sufficient new financing.
- There are various maturity dates associated with our 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 our indebtedness. Further, there is no assurance that future refinancing or renegotiation of our senior credit facilities, senior notes or other debt facilities, or additional agreements will not have materially different or more stringent terms. See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.
- We cannot guarantee that we will buy back our ordinary shares pursuant to our recently announced share repurchase plan or that our share repurchase plan will enhance long-term shareholder value.

On October 22, 2015, our Board of Directors authorized a $2.0 billion share repurchase plan. During the three months ended December 31, 2015, we repurchased shares through the plan totaling $500.0 million. The remaining $1.5 billion in repurchases may extend through the year ended December 31, 2018. Though we anticipate that we will complete the purchase of the remaining $1.5 billion in shares in accordance with the announced timeline, the specific timing and amount of buybacks, if any, will depend upon several factors, including market and business conditions, the trading price of our ordinary shares, and, with respect to the expected repurchases in 2016 and beyond, the nature of other investment opportunities. Buybacks of our ordinary shares pursuant to our share repurchase plan could affect the market price of our ordinary shares or increase their volatility. Additionally, our share repurchase plan could diminish our cash reserves, which may impact our ability to finance future growth and to pursue possible future strategic opportunities and acquisitions. Although our share repurchase plan is intended to enhance long-term shareholder value, there is no assurance that it will do so, and short-term share price fluctuations could reduce the plan's effectiveness.

- Any additional shares we may issue could dilute your ownership in the Company.

Under Irish law, our authorized share capital can be increased by an ordinary resolution of our shareholders, and the directors may issue new ordinary or preferred shares up to a maximum amount equal to the authorized but unissued share capital, without shareholder approval, once authorized to do so by the articles of association or by an ordinary resolution of our shareholders.

- Subject to specified exceptions, Irish law grants statutory preemption rights to existing shareholders to subscribe for new issuances of shares for cash, but allows shareholders to authorize the waiver of the statutory preemption rights by way of special resolution with respect to any particular allotment of shares.

Our articles of association contain, as permitted by Irish company law, a provision authorizing the board to issue new shares for cash without offering preemption rights. The authorization of the directors to issue shares and the authorization of the waiver of the statutory preemption rights must both be renewed by the shareholders at least every five years, and we cannot provide any assurance that these authorizations will always be approved, which could limit our ability to issue equity and thereby adversely affect the holders of our securities.

- We are incorporated in Ireland; Irish law differs from the laws in effect in the United States and may afford less protection to, or otherwise adversely affect, our shareholders.

As an Irish company, we are governed by the Irish Companies Act 2014 (the "Act"). The Act differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, mergers, amalgamations and acquisitions, takeovers, shareholder lawsuits, and indemnification of directors.

- Under Irish law, the duties of directors and officers of a company are generally owed to the company only. As a result, shareholders of Irish companies do not have the right to bring an action against the directors or officers of a company, except in limited circumstances.

- Depending on the circumstances, shareholders may be subject to different or additional tax consequences under Irish law as a result of the acquisition, ownership and/or disposition of ordinary shares, including, but not limited to, Irish stamp duty, dividend withholding tax, and capital acquisitions tax.

- There is no treaty between Ireland and the U.S. providing for the reciprocal enforcement of foreign judgments. Before a foreign judgment would be deemed enforceable in Ireland, the judgment must be provided by a court of competent jurisdiction and be for a final and conclusive sum. An Irish court may exercise its right to refuse to recognize and enforce a foreign judgment if the foreign judgment was obtained by fraud, if it violated Irish public policy, if it is in breach of natural justice, or if it is irreconcilable with an earlier judgment.

- An Irish court may stay proceedings if concurrent proceedings are being brought elsewhere. Judgments of U.S. courts of liabilities predicated upon U.S. federal securities laws may not be enforced by Irish courts if deemed to be contrary to public policy in Ireland.

- We are subject to Irish takeover rules under which our Board of Directors is not permitted to take any action without Irish Takeover Panel approval that might frustrate an offer for our ordinary shares once we have received an approach that may lead to an offer, or have reason to believe an offer is imminent. Further, it could be more difficult for us to obtain shareholder approval for a merger or negotiated transaction than if we were a U.S. company because the shareholder approval requirements for certain types of transactions differ, and in some cases are greater, under Irish law.

We may be limited in our ability to pay dividends in the future.

A number of factors may limit our ability to pay dividends in the future, including:

- The availability of distributable reserves, as approved by our shareholders and the Irish High Court;

- Our ability to receive cash dividends and distributions from our subsidiaries

- Compliance with applicable laws and debt covenants; and

- Our financial condition, results of operations, capital requirements, general business conditions, and other factors that our Board of Directors may deem relevant.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Perrigo Company plc - Item 2

ITEM 2. PROPERTIES

Our world headquarters is located in Dublin, Ireland, and our main administrative offices are located in Allegan, Michigan. We manufacture products at 30 worldwide locations and have R&D, logistics, and office support facilities in many of the regions in which we operate. We own approximately 59% of our facilities and lease the remainder. Our primary facilities by geographic area were as follows at December 31, 2015:

Country	Number of Facilities	Segment(s) Supported
Ireland	1	CHC, Rx, Specialty Sciences
United States	52	CHC, Rx
Mexico	9	CHC
Israel	5	CHC, Rx, Other
France	4	BCH
Belgium	4	BCH
Australia	4	CHC
United Kingdom	4	CHC, Rx
Germany	3	BCH
Netherlands	2	BCH
India	1	Other
Austria	1	BCH
Poland	1	BCH
Switzerland	1	BCH
Greece	1	BCH

We believe that our production facilities are adequate to support the business, and our property and equipment are well maintained. Our manufacturing plants are suitable for their intended purposes and have capacities and projected capacities adequate for current and projected needs of our existing products.

ITEM 3. LEGAL PROCEEDINGS

Information regarding our current legal proceedings is presented in Item 8. Note 16.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ADDITIONAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers and their ages and positions as of February 19, 2016 were:

Name	Age	Position
Douglas S. Boothe	52	Executive Vice President, General Manager, Prescription Pharmaceuticals
Judy L. Brown	47	Executive Vice President, Chief Financial Officer
Marc Coucke [(1)]	51	Executive Vice President, General Manager, Branded Consumer Healthcare
Thomas M. Farrington	58	Executive Vice President, Chief Information Officer
John T. Hendrickson	52	President
Todd W. Kingma	56	Executive Vice President, General Counsel and Secretary
Sharon Kochan	47	Executive Vice President, General Manager, International
Jeffrey R. Needham	59	Executive Vice President, General Manager, Consumer Healthcare
Joseph C. Papa	60	Chairman, Chief Executive Officer

(1) Employed by Mylecke Management, Art & Invest N.V.

Perrigo Company plc - Additional Item
Executive Officers

Mr. Boothe was named Executive Vice President, General Manager, Prescription Pharmaceuticals in January 2013. Prior to joining us, Mr. Boothe was Chief Executive Officer of Actavis Inc. from August 2008 to December 2012, where he was responsible for all aspects of its generics business in North America and Latin America, and Chief Operating Officer of Actavis Inc. from 2006 to 2008. He also has held a series of leadership roles at Alpharma Inc., Pharmacia Corporation, and Xerox Corporation. Mr. Boothe is a director of Evclid Systems, a privately-owned leader in myopic lens solutions.

Ms. Brown was named Executive Vice President, Chief Financial Officer in July 2006. She served as Vice President and Corporate Controller from September 2004 to July 2006. Previously, Ms. Brown held various senior positions in finance and operations at Whirlpool Corporation from 1998 to August 2004 and prior to that worked for Ernst & Young LLP in the U.S. and Germany. Ms. Brown is a director of Belden Corporation, an NYSE traded company, that is a global leader in high quality, end-to-end signal transmission solutions and network infrastructure needs for industrial, enterprise, and broadcast markets.

Mr. Coucke was named Executive Vice President, General Manager, Branded Consumer Healthcare in March 2015. He was elected as a director of Perrigo Company plc in November 2015. He served as Omega's Chairman and Chief Executive Officer since 1987 until we acquired Omega in March 2015. Omega was founded in 1987 by Mr. Coucke and two other Belgian pharmacists and focused on the production and sales of various shampoos. Under Mr. Coucke’s leadership, the company grew and expanded geographically into a world player of consumer healthcare products, with affiliates in 36 countries. He is a qualified pharmacist (RUG). Mr. Coucke is acting as permanent representative of Mylecke Management, Art & Invest N.V.

Mr. Farrington was named Senior Vice President, Chief Information Officer in October 2006 and promoted to Executive Vice President in 2015. He formerly served as Chief Information Officer for F. Dohmen Co. in addition to serving as a division President for JASCORP LLC from 2003 to October 2006. Prior to that position, Mr. Farrington held various senior positions in information technology and finance at Dell, Inc. from 1999 to 2003.

Mr. Hendrickson was named President in October 2015. He served as Executive Vice President, Global Operations and Supply Chain from October 2009 to October 2015, and previously served as Executive Vice President and General Manager, Consumer Healthcare from March 2007 to October 2009. He served as Executive Vice President of Operations from 1999 to 2007. Mr. Hendrickson began his employment with us in 1989.

Mr. Kingma was named Executive Vice President, General Counsel and Secretary in May 2006. He served as Vice President, General Counsel and Secretary from 2003 to May 2006. Previously, Mr. Kingma held various positions at Pharmacia Corporation from 1991 through 2003. His last position with Pharmacia Corporation was Vice President and Associate General Counsel, Global Specialty Operations.

Mr. Kochan was named Executive Vice President, General Manager, International in August 2012. He served as Executive Vice President, General Manager of Prescription Pharmaceuticals from March 2007 to July 2012 and as Senior Vice President of Business Development and Strategy from 2005 to March 2007. Mr. Kochan was Vice President, Business Development of Agis Industries (1983) Ltd. from 2001 until we acquired Agis in 2005.

Mr. Needham was named Executive Vice President, General Manager, Consumer Healthcare in October 2009. He served as Senior Vice President of Commercial Business Development from 2005 through October 2009. Previously, he served as Senior Vice President of International from 2004 to 2005. He served as Managing Director of our U.K. operations from 2002 to 2004 and as Vice President of Marketing from 1993 to 2002.

Mr. Papa was named Chairman and Chief Executive Officer of Perrigo Company plc in October 2015. He joined us in October 2006 as President and Chief Executive Officer. Mr. Papa was elected a director in November 2006 and, subsequently, was appointed as Chairman of the Board of Directors in October 2007. Previously, Mr. Papa served from 2004 to October 2006 as Chairman and Chief Executive Officer of the Pharmaceutical and Technologies Services segment of Cardinal Health, Inc. Prior to that position, he served as President and Chief Operating Officer of Watson Pharmaceuticals, Inc. from 2001 to 2004. Additionally, Mr. Papa has held management positions at DuPont Pharmaceuticals, Pharmacia Corporation, G.D. Searle & Company and Novartis AG. Mr. Papa is a director of Smith & Nephew, a developer of advanced medical devices.

Perrigo Company plc - Item 5

PART II.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

On and prior to December 18, 2013, our common stock consisted of shares of Perrigo Company, a Michigan Corporation, and since December 19, 2013, our common equity consists of ordinary shares of Perrigo Company plc, incorporated under the laws of Ireland.

Prior to June 6, 2013, our common equity traded on the NASDAQ Global Select Market ("NASDAQ") under the symbol PRGO. Since June 6, 2013, our common equity has traded on the New York Stock Exchange ("NYSE") under the symbol PRGO. In association with the acquisition of Agis Industries (1983) Ltd., our common equity has been trading on the Tel Aviv Stock Exchange ("TASE") since March 16, 2005. As of February 19, 2016, there were 2,461 record holders of our ordinary shares.

Set forth below are the high and low sale prices for our ordinary shares by the NYSE for the periods indicated:

	Six Months Ended December 31, 2015		Fiscal Years Ended June 27, 2015		June 28, 2014	
	High	Low	High	Low	High	Low
First quarter	$198.42	$158.35	$160.65	$135.00	$134.31	$115.94
Second quarter	$167.92	$140.40	$171.57	$142.38	$157.47	$122.56
Third quarter	N/A	N/A	$174.65	$147.21	$168.39	$144.46
Fourth quarter	N/A	N/A	$205.72	$161.86	$158.99	$125.37

The graph below shows a comparison of our cumulative total return with the cumulative total returns for the S&P 500 Index and the S&P Pharmaceuticals Index. The graph assumes an investment of $100 at the beginning of the period and the reinvestment of any dividends. Information in the graph is presented for the years ended December 31, 2010 through December 31, 2015.

Perrigo Company plc - Item 5

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
AMONG PERRIGO COMPANY PLC**, THE S&P 500 INDEX, AND THE S&P PHARMACEUTICALS INDEX

	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015
Perrigo Company plc	$100.00	$154.17	$165.35	$244.62	$267.21	$231.99
S&P 500	$100.00	$102.11	$118.45	$156.82	$178.29	$180.75
S&P Pharmaceuticals	$100.00	$117.76	$134.75	$182.22	$222.70	$235.59

* $100 invested on December 31, 2010 in stock or index - including reinvestment of dividends. Indexes calculated on month-end basis.

** Perrigo Company prior to December 18, 2013. Perrigo Company plc beginning December 18, 2013.

In January 2003, the Board of Directors adopted a policy of paying quarterly dividends. We paid dividends of $36.3 million ($0.25 per share) and $29.0 million ($0.21 per share) during the six months ended December 31, 2015 and December 27, 2014, respectively, and $64.8 million ($0.46 per share), $46.1 million ($0.39 per share), and $33.0 million ($0.35 per share) for the fiscal years ended June 27, 2015, June 28, 2014, and June 29, 2013, respectively. The declaration and payment of dividends and the amount paid, if any, are subject to the discretion of the Board of Directors and depend on our earnings, financial condition, capital and surplus requirements and other factors the Board of Directors may consider relevant.

In October 2015, the Board of Directors approved a share repurchase plan of up to $2.0 billion. During the six months ended December 31, 2015, we repurchased 3.3 million ordinary shares at an average repurchase price of $151.59 per share, for a total of $500.0 million.

Perrigo Company plc - Item 5

Share repurchase activity during the three months ended December 31, 2015 was as follows (in millions, except per share amounts):

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans	Value of Shares Available for Purchase [1]
September 27 - October 31, 2015	—	$—	—	
November 1 - November 28, 2015	3.3	$151.59	3.3	
November 29 - December 31, 2015	—	$—	—	
Total	3.3			$1,500.0

(1) The remaining $1.5 billion in the table represents the amount available to repurchase shares under our authorized share repurchase plan as of December 31, 2015.

ITEM 6. SELECTED FINANCIAL DATA

The Consolidated Statement of Operations data set forth below with respect to the six months ended December 31, 2015 and December 27, 2014, and the fiscal years ended June 27, 2015, June 28, 2014, and June 29, 2013 and the Consolidated Balance Sheet data at December 31, 2015, June 27, 2015, and June 28, 2014 are derived from and are qualified by reference to the audited consolidated financial statements included in Item 8 of this report and should be read in conjunction with those financial statements and notes. The Consolidated Statement of Operations set forth below with respect to the fiscal years ended June 30, 2012 and June 25, 2011, and the Consolidated Balance Sheet data at June 29, 2013, June 30, 2012, and June 25, 2011, are derived from audited consolidated financial statements not included in this report. For all years presented, the Consolidated Balance Sheet data has been adjusted for the retrospective application of a change in accounting policy to reclassify deferred financing fees from Other non-current assets to Long-term debt, as further described in Item 8. Note 1.

	Six Months Ended		Fiscal Years Ended				
(in millions, except per share amounts)	December 31, 2015[1]	December 27, 2014[2]	June 27, 2015[3]	June 28, 2014[4]	June 29, 2013[5]	June 30, 2012[6]	June 25, 2011
Statement of Operations Data							
Net sales	$2,769.5	$					