PERRIGO Co plc
Form 10-K
February 27, 2019
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prgo:defendant

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the year ended December 31, 2018
or
[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
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.)
The Sharp Building, Hogan Place, 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 every Interactive Data File required to be submitted 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 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-K or any amendment to this Form 10-K. **[ ]**

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.
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Large accelerated filer **[X]** Accelerated filer **[ ]** Non-accelerated filer **[ ]** Smaller reporting company **[ ]**

Emerging growth company **[ ]**

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. **[ ]**

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 June 29, 2018 as reported on the New York Stock Exchange, was $10,034,430,689. 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 22, 2019, the registrant had 135,873,069 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-K.

PERRIGO COMPANY PLC
FORM 10-K
YEAR ENDED DECEMBER 31, 2018
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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,” "forecas “predict,” “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, including: the timing, amount and cost of any share repurchases; future impairment charges; the success of management transition; customer acceptance of new products; competition from other industry participants, some of whom have greater marketing resources or larger market shares in certain product categories than we do; pricing pressures from customers and consumers; resolution of uncertain tax positions, including the Company's appeal of the Notice of Assessment ("NoA") issued by the Irish Office of the Revenue Commissioners (“Irish Revenue”) and the impact that an adverse result in such proceedings would have on operating results, cash flows and liquidity; potential third-party claims and litigation, including litigation relating to our restatement of previously-filed financial information and litigation relating to uncertain tax positions, including the NoA; potential impacts of ongoing or future government investigations and regulatory initiatives; the impact of tax reform legislation and healthcare policy; general economic conditions; fluctuations in currency exchange rates and interest rates; the consummation of announced acquisitions or dispositions and the success of such transactions, and our ability to realize the desired benefits thereof; and our ability to execute and achieve the desired benefits of announced cost-reduction efforts, strategic and other initiatives. Statements regarding the separation of the RX business, including the expected benefits, anticipated timing, form of any such separation and whether the separation ultimately occurs, are all subject to various risks and uncertainties, including future financial and operating results, our ability to separate the business, the effect of existing interdependencies with our manufacturing and shared service operations, and the tax consequences of the planned separation to us or our shareholders. Furthermore, we may incur additional tax liabilities in respect of 2016 and prior years or be found to have breached certain provisions of Irish company law in connection with our restatement of our previously filed financial statements, which may result in additional expenses and penalties. These and other important factors, including those discussed in this report under “Risk Factors” and in any subsequent filings with the United States 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, TRADE NAMES 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, trade names, and service marks 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.

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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"). 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 healthcare company that has been delivering value to our customers and consumers by providing Quality Affordable Healthcare Products®. Founded in 1887 as a packager of home remedies, we have built a unique business model that is best described as the convergence of a fast-moving consumer goods company, a high-quality pharmaceutical manufacturing organization and a world-class supply chain network. We are one of the world's largest manufacturers of over-the-counter (“OTC”) healthcare products and suppliers of infant formulas for the store brand market. We are also a leading provider of branded consumer health and wellness products throughout Europe and a leading producer of generic prescription pharmaceutical topical products such as creams, lotions, gels, and nasal sprays ("extended topicals"). We are headquartered in Ireland and sell our products primarily in North America and Europe, as well as in other markets, including Israel, Mexico, Australia, and Canada.

Segments

Our operating and reportable segments are as follows:

- **Consumer Healthcare Americas** (**"CHCA"**), comprises our U.S., Mexico and Canada consumer healthcare business (OTC, contract manufacturing, infant formula and animal health categories).
- **Consumer Healthcare International** (**"CHCI"**), comprises our branded consumer healthcare business primarily in Europe and our consumer focused businesses in the United Kingdom ("U.K."), Australia, and Israel. This segment also includes our U.K. liquid licensed products business.
- **Prescription Pharmaceuticals** (**"RX"**), comprises our U.S. Prescription Pharmaceuticals business.

We previously had two legacy segments, Specialty Sciences and Other, which contained our Tysabri® financial asset and API businesses, respectively, which we divested. Following these divestitures, there were no substantial assets or operations left in either of these segments. Effective January 1, 2017, all expenses associated with our former Specialty Sciences segment were moved to unallocated expenses. Financial information related to our business segments can be found in Item 8. Note 19. Our segments reflect the way in which our management makes operating decisions, allocates resources and manages the growth and profitability of the Company.

MAJOR DEVELOPMENTS IN OUR BUSINESS

Vision Transformation

Upon the arrival of our new CEO and President Murray Kessler, he and his leadership team made their first priority to set a new vision for the Company that will help us transform into a consumer-focused company. That vision is "To make lives better by bringing "*Quality, Affordable Self-Care Products™"* that consumers trust everywhere they are sold." The new vision for the future is designed to support the shifting focus on our consumer branded and store brand portfolio and our global reach and the opportunities for growth we see ahead of us, while remaining loyal to our heritage. The vision represents an evolution from healthcare to self-care, which takes advantage of a massive global trend and opens up a large number of adjacent growth opportunities for the Company.

Irish Tax Appeals Commission Notice of Amended Assessment

Perrigo Pharma International, a designated activity company organized under the laws of Ireland, formerly known as Elan Pharma International Limited (“Elan Pharma”) and currently a subsidiary of Perrigo Company plc, timely filed an appeal on December 27, 2018 with the Irish Tax Appeals Commission regarding a NoA issued by the Irish Office of the Revenue Commissioners (“Irish Revenue”) for the calendar year ended December 31, 2013. The NoA is dated November 29, 2018, and assesses an Irish corporation tax liability against Elan Pharma in the amount of €1,636 million, not including interest or any applicable penalties.

Perrigo acquired Elan Pharma through the December 2013 business combination between Perrigo’s predecessor and Elan Corporation, plc. The NoA relates to the tax treatment of the April 2013 sale by Elan Pharma of Tysabri® intellectual property and related assets to Biogen Idec. As previously reported, the consideration paid by Biogen Idec took the form of an upfront payment and future contingent payments. The upfront payment received from Biogen Idec in 2013 and contingent payments received in subsequent years were recognized as trading income in Elan Pharma’s tax returns filed with Irish Revenue. This treatment is consistent with Elan Pharma’s activities for two decades relating to the active management of intellectual property rights, which includes acquiring,
developing, holding, exploiting, dealing in and disposing of intellectual property rights for use in the pharmaceutical industry.

On October 30, 2018, Irish Revenue issued an audit findings letter to Elan Pharma asserting the claim that (a) IP sales transactions by Elan Pharma, including the sale of Tysabri®, were not part of the trade of Elan Pharma and therefore should have been treated as chargeable gains subject to an effective 33% tax rate, rather than the 12.5% tax rate applicable to trading income, and (b) all amounts received in respect of both the Tysabri® transaction and the related transaction entered into with RPI Finance Trust in 2017 should be taxed in Elan Pharma’s 2013 tax year.

We disagree with both the basis on which Elan Pharma has been assessed and the methodology used to calculate the amount set out in the NoA. We believe the NoA is without merit and that Irish Revenue’s position is incorrect as a matter of law. Accordingly, we filed an appeal of the NoA on December 27, 2018 and will pursue all available administrative and judicial avenues as may be necessary or appropriate. As part of this strategy to pursue all available administrative and judicial avenues, Elan Pharma was, on February 25, 2019, granted leave by the Irish High Court to seek judicial review of the issuance of the NoA. The judicial review filing is based on our belief that Elan Pharma's legitimate expectations as a taxpayer have been breached, not on the merits of the NoA itself. If we are ultimately successful in the judicial review proceedings, the NoA will be invalidated and Irish Revenue will not be able to re-issue the NoA. The proceedings before the Tax Appeals Commission has been stayed until a decision on the judicial review application has been made, which could take up to, or more than, a year. No payment of any amount related to this assessment is required to be made, if at all, until all applicable proceedings

have been completed, which could take a number of years. However, while we believe our position to be correct, there can be no assurance of an ultimate favorable outcome, and if the matter is ultimately resolved unfavorably it would have a material adverse impact on us, including on liquidity and capital resources (refer to Item 1A. Risk Factors - Tax related Risks and Item 8. Note 14).

RX Separation

On August 9, 2018, we announced a plan to separate our RX business, which, when completed, will enable us to focus on expanding our consumer-facing businesses. We have begun the preparations for the separation, which may include a possible sale, spin-off, merger or other form of separation. While we are currently targeting to complete the separation by the end of 2019, the form of separation may delay its completion beyond this date. In connection with the proposed separation, we anticipate incurring significant preparation costs, excluding restructuring expenses and transaction costs, in the range of $45.0 million to $80.0 million depending on the final structure of a transaction, with a spin-off resulting in costs at the higher end of this range.

API Divestitures

During the year ended December 31, 2017, we completed the sale of our India API business to Strides Shasun Limited for $22.2 million in proceeds. Prior to closing the sale, we determined that the carrying value of the India API business exceeded its fair value less the cost to sell, resulting in an impairment charge of $35.3 million, which was recorded in Impairment charges on the Consolidated Statements of Operations for the year ended December 31, 2016.

During the year ended December 31, 2017, we completed the sale of our Israel API business to SK Capital, for a sale price of $110.0 million.

Financial Asset

During the year ended December 31, 2016, we initiated a strategic review of the Tysabri® financial asset and identified impairment indicators of the fair value of that royalty stream, which led to a goodwill impairment of $199.6 million, which was recorded in Impairment charges on the Consolidated Statements of Operations. During the year ended December 31, 2017, we divested the Tysabri® financial asset to Royalty Pharma for up to $2.85 billion, consisting of $2.2 billion in cash and up to $250.0 million and $400.0 million in milestone payments. As a result of this transaction, we transferred the entire financial asset to Royalty Pharma and recorded a $17.1 million gain. We elected to account for the contingent milestone payments using the fair value option method, and these were recorded at an estimated fair value of $134.5 million as of December 31, 2017. During the year ended December 31, 2018, Tysabri® met the 2018 global net sales threshold resulting in a $170.1 million gain recorded in Change in financial assets. We received the $250.0 million royalty payment on February 22, 2019. In order for us to receive the 2020 milestone payment, Royalty Pharma contingent payments for Tysabri® sales in 2020 must exceed $351.0 million. The fair value of the 2020 milestone payment is $73.2 million as of December 31, 2018.

Omega Acquisition

On March 30, 2015, we acquired Omega Pharma Invest N.V. ("Omega"), one of the largest OTC companies in Europe, for $3.0 billion in equity and cash and assumed debt of $1.6 billion, for a total

purchase price of $4.6 billion. 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 net sales and cash flow streams.

The broader European platform established through the Omega acquisition facilitated the acquisition of a portfolio of well-established OTC brands sold primarily in Europe from GlaxoSmithKline Consumer Healthcare (“GSK”), on August 28, 2015, as well as Naturwohl Pharma, GmbH ("Naturwohl"), with its leading German dietary supplement brand Yokebe®, on September 15, 2015.

During the year ended December 31, 2016, we identified impairment indicators associated with certain intangible assets and goodwill, which required us to test these assets for impairment. As a result, we recorded total impairments of $2.0 billion which was recorded in Impairment charges on the Consolidated Statements of Operations (refer to Item 8. Note 4).

NEW PRODUCTS

We consider a product to be new if it (i) was reformulated, (ii) was a product line extension due to changes in characteristics such as strength, flavor, or color, (iii) had a change in product status from "prescription only" ("Rx") to OTC, (iv) was a new store brand or branded launch, (v) was provided in a new dosage form or (vi) was sold to a new geographic area with different regulatory authorities, in all cases, within 12 months prior to the end of the period for which net sales are being measured. During the year ended December 31, 2018, new product sales were $169.7 million.

CONSUMER HEALTHCARE AMERICAS

Overview

The CHCA segment is focused primarily on the sale of store-brand products, including OTC cough, cold, allergy and sinus, analgesic, gastrointestinal, smoking cessation, infant formula and food, diagnostic products, and animal health products in the U.S., Mexico and Canada. We are a leading provider of consumer healthcare products sold to consumers via store brands as well as consumer healthcare products under our own brands. Consumer awareness and knowledge of the quality and value that OTC store brand products represent continues to grow due to efforts to promote their own label programs. During the year ended December 31, 2018, our CHCA segment represented approximately 51% of consolidated net sales.

The CHCA segment develops, manufactures, and markets store-brand 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 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 continuing to be the leader in developing and marketing new store brand products, including infant formula, 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 a competitor filing an ANDA. 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-marketing approval.

The CHCA segment also develops, manufactures, and distributes certain branded products, which is consistent with the segment's healthcare strategy to meet consumer needs wherever they are sold. Branded products are sold under the brand names Good Sense®, Sergeant's®, Sentry®, Zephrex D®, PetArmor®, and ScarAway® brand names.

We manufacture a significant portion of our CHCA segment's products at our plants in the U.S., Mexico, and Israel, and we source the remaining product materials 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 the increasing age of the population, in combination with continued rising healthcare costs, will drive the need for the greater value that our store brand products provide consumers. In addition, we believe that new products and products switching from Rx to OTC (as described above) will continue to drive growth within the segment.

Recent Developments

- On May 29, 2018, we entered into a license agreement with Merck Sharp & Dohme Corp. ("Merck") that will allow us to develop and commercialize an OTC version of Nasonex-branded products, as well as other products containing the same active ingredient. In connection with this license agreement, we paid an upfront license fee of $50.0 million. In addition, if we achieve certain development milestones, we will make future milestone and royalty payments.

- During the year ended December 31, 2018, we identified indications of impairment in the animal health reporting unit. The impairment indicators related to changes in channel dynamics, a strategic decision to re-prioritize our brands, and a decline in the forecasted outlook of the reporting unit. We recorded goodwill and intangible asset impairment charges of $213.3 million in Impairment charges on the Consolidated Statements of Operations.

Products

Our CHCA segment offers products in the following categories:

Product Category	Description
Analgesics	Pain relievers and fever reducers
Cough/cold/allergy/sinus	Cough suppressant, chest expectorant, sinus and pain pressure relief
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

The chart below reflects net sales by product category in the CHCA segment, which includes net sales from our OTC contract manufacturing business for the year ended December 31, 2018.

We launched a number of new CHCA products in the year ended December 31, 2018, most notably esomeprazole magnesium (store brand equivalent to Nexium® 24HR capsules), omeprazole delayed release orally disintegrating tablets, and infant formula products. During the year ended December 31, 2018, new product sales in the CHCA segment were $48.7 million.

We, on our own or in conjunction with partners, received final FDA approval from U.S. health authorities for four new products within the CHCA segment in the year ended December 31, 2018, and as of December 31, 2018, we had eight new product applications pending FDA approval.

Sales and Marketing

Our customers include major global, national, and regional retail drug, supermarket, and mass merchandise chains such as Walmart, Costco, Kroger, Target, CVS, Walgreens Boots Alliance, Dollar General, Sam’s Club, Rite Aid, Amazon, Aldi, Petsmart, and Petco, and major wholesalers, including McKesson, Amerisource Bergen, and Cardinal Health.

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 CHCA segment employs its own sales force to service larger customers, and uses industry brokers for other customers. 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 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 and market share 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. As eCommerce continues to grow as a consumer channel for our products, we are developing resources, programs and tools to be a strategic marketing partner for our customers' digital marketing efforts.

In contrast with national brand manufacturers, which incur considerable advertising and marketing expenditures targeted directly to the end user or consumer, the CHCA 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, online 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, smoking cessation, and infant formula are highly competitive and differ for each product line and geographic region. Our primary competitors include manufacturers, such as LNK International, Inc., PL Developments, and Dr. Reddy's Labs, and brand-name pharmaceutical and consumer product companies, such as Johnson & Johnson, Pfizer, Bayer AG, GSK, Nestle S.A. (Gerber), Abbott Nutrition, Aurobindo, 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 (refer to Item 1A. Risk Factors - Risks Related to Operations for additional information and risks associated with competition).

CONSUMER HEALTHCARE INTERNATIONAL

Overview

The CHCI segment is comprised of our branded consumer products across self-care, skin care, and lifestyle products primarily in Europe and our consumer focused businesses in the U.K., Australia, and Israel. This segment also includes our U.K. liquid licensed generic product business. The CHCI segment develops, manufactures, markets and distributes many well-known European consumer healthcare brands in the cough, cold, allergy, sinus, lifestyle, personal care and derma-therapeutics, natural health and vitamins, smoking cessation, and anti-parasite categories. In addition, the segment leverages its broad

regulatory, sales, and distribution infrastructure to in-license and sell third-party brands and generic pharmaceutical products. The CHCI segment distributes these products through an extensive network of customers including pharmacies, wholesalers, drug and grocery store retailers, and para-pharmacies in 27 countries, primarily in Europe. Many CHCI products have market leading positions in the markets in which they compete. During the year ended December 31, 2018, the CHCI segment represented approximately 32% of consolidated net sales.

Through continued investment in R&D partnerships and new technologies, the CHCI segment strives to offer high quality products that meet consumers' needs. The combination of internal R&D, new product development, insourcing, acquisitions, and partnerships support the new product pipeline, both in terms of brand extensions and product improvements. In the U.K., R&D focuses on oral liquid formulations for the branded Rx products for which liquid formulations are not available, as well as the development of store brand products and

products for the branded business. Additional R&D centers are located in France, Sweden, Austria, and Belgium. In the rest of Europe, 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.

The CHCI segment primarily focuses on building local and regional 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 large scale pharmacy chains. Additionally, the absence of a centralized regulatory environment within Europe adds to the complexity of obtaining approvals for products in these markets.

While the CHCI segment sells products from over 200 brands both on its own and through third parties, it focuses its resources on its "Focus 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

- Management continues to implement its previously disclosed strategy for brand prioritization, sales force restructuring, and manufacturing insourcing, which is expected to reduce selling costs, improve operating margins and focus on higher value OTC products. As part of this strategy, we implemented a new restructuring plan in our CHCI segment that is expected to improve our cost structure.

Products

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

Product Category	Description	Focus Brands
Cough, Cold, Allergy, and Sinus	Products that address pain relief and respiratory symptoms, including traditional medications and alternative treatments such as aromatherapy solutions.	Bittner®/Aflubin® Bronchenolo®/Bronchostop® Libenar® Physiomer® Phytsosun®/Valda® Solpadeine®/Coldrex®/Antigrippine®
Lifestyle	Weight management, pregnancy and fertility kits, sleep management, smoking cessation, and eye care.	Niquitin® Silence®/Nytol® XLS (Medical)®
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® Biodermal® Canoderm® Dermalex® Lactacyd® Wartner®
Natural Health and Vitamins, Minerals, and Supplements	Vitamins, minerals, supplements, and various other natural remedies.	Abtei® Biover® Davitamon® Granufink® Ymea®

Anti-Parasite	Products focused on the elimination of parasites in both humans and pets including lice treatment and insect repellent.	Jungle Formula® Paranix®

The chart below reflects net sales by product category in the CHCI segment for the year ended December 31, 2018.

We launched a number of new CHCI products in the year ended December 31, 2018, most notably Phytsosun®, Paranix®, and ACO®. During the year ended December 31, 2018, new product sales in the CHCI segment were $77.8 million.

The CHCI segment has more than 100 strategic new products in 12 product categories in development, with each of its Focus brands having a five-year innovation master plan.

Sales and Marketing

Our customers include pharmacies, drug stores, and grocery stores located primarily in Europe, including Walgreens Boots Alliance, ASDA, Tesco, DM, Rossmann, ETOS, and Kruidvat. The CHCI segment sells its products primarily through an established pharmacy sales force to an extensive network of individual pharmacists. Our sales representatives visit pharmacists frequently, 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 local sales representatives to improve our brands' presence and recognition. We seek to attract key talent from leading OTC, Fast Moving Consumer Goods ("FMCG"), and retailer companies to build strong local teams throughout the countries in which the CHCI segment operates.

While CHCI products have a higher average gross margin than products sold by the CHCA segment, selling expenses are significantly higher due to the sales force mentioned above, as well as broadcast advertising and point-of-sale promotional spending to enhance brand equity. Key marketing communication tools for the CHCI segment include television and digital commercials, consumer leaflets, product websites, and targeted promotional campaigns.

Competition

The competitive landscape of the European consumer products market, in the categories in which we compete, 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 CHCI segment's markets is both local and

global. Competitors include Sanofi, Bayer, Reckitt Benckiser, GSK, Novartis, and Johnson & Johnson, as well 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 (refer to 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 prescription drugs primarily in the U.S. We define this portfolio as predominantly "extended topicals" as it encompasses a broad array of dosage forms such as creams, ointments, lotions, gels, shampoos, foams, suppositories, sprays, liquids, suspensions, and solutions. The portfolio also includes select controlled substances, injectables, hormones, oral solid dosage forms, and oral liquid formulations. During the year ended December 31, 2018, the RX segment represented approximately 17% of consolidated net sales.

In addition to extended topical products, 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 substances and hormonal products. R&D efforts focus on complex formulations, many of which require costly clinical endpoint trials.

We manufacture our topical and oral products in the U.S. and Israel, 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 may be eligible for 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 (refer to Item 8. Note 2 for more 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 collaboration agreements).

Recent Trends and Developments

- We continue to experience a significant year-over-year reduction in pricing in our RX segment due to competitive pressures. This softness in pricing is attributable to various factors, including increased focus from customers to capture competition in specific products, supply chain productivity savings, and consolidation of certain customers. While in the fourth quarter of 2018, we experienced a year-over-year

decrease in pricing pressure, we expect softness in pricing to continue to impact the segment for the foreseeable future.

On August 9, 2018, we announced a plan to separate our RX business, which, when completed, will enable us to focus on expanding our consumer-facing businesses. We have begun the preparations for the separation, which may include a possible sale, spin-off, merger or other form of separation. While we are currently targeting to complete the separation by the end of 2019, the form of separation may delay its completion beyond this date. In connection with the proposed separation, we anticipate incurring significant preparation costs, excluding restructuring expenses and transaction costs, in the range of $45.0 million to $80.0 million depending on the final structure of a transaction, with a spin-off resulting in costs at the higher end of this range.

Perrigo Company plc - Item 1
RX

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	BenzaClin™
Budesonide	Entocort®
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®
Olopatadine nasal spray	Patanase®
Permethrin cream	Elimite®
Scopolamine patch	TransdermScop®
Tacrolimus	Protopic®
Testosterone 1.62% gel	Androgel®
Testosterone cypionate injection	Depo®, Testosterone
Testosterone solution	Axiron®
Triamcinolone acetonide nasal spray	Nasacort® AQ
Triamcinolone cream/ointment	Triderm™/Kenalog™
Tretinoin Cream and Gel	Retin-A®

(1) Contains the same active ingredients present in the same dosage form as the comparable brand-name drug

We launched a number of new RX products in the year ended December 31, 2018, most notably Testosterone Gel 1.62% (generic equivalent to Androgel®). During the year ended December 31, 2018, new product sales in the RX segment were $43.2 million.

During the year ended December 31, 2018, we, on our own or in collaboration with partners, received final approval from FDA health authorities for four Rx drug applications, and as of December 31, 2018, we had 27 Rx drug applications pending approval.

Sales and Marketing

Our customers include sourcing groups such as Red Oak, WBAD and ClarusONE, major wholesalers, national and regional retail drug, supermarket and mass merchandise chains, hospitals, and pharmacies.

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 Taro Pharmaceuticals, Mylan, Teva Pharmaceutical Industries Ltd., Glenmark Generics Inc., Akorn, Lupin, and Apotex Corp.

We believe that one of our primary competitive advantages is our ability to introduce difficult to develop and/or manufacture topical 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 for high quality products (refer to Item 1A. Risk Factors - Risks Related to Operations for more information and risks associated with competition).

INFORMATION APPLICABLE TO ALL REPORTABLE SEGMENTS

Trademarks, Patents and Licensing Agreements

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 may be more limited, as they are available from one or only a few suppliers and may require regulatory approval before we can use them. Prior to the sale of our Israel and India API businesses, we had the ability to manufacture and supply certain API for our OTC and Rx products, which we now source from the companies that have acquired our API businesses. We have been purchasing an increasing number of components and select finished goods rather than manufacturing them because of the availability of goods, economic reasons, temporary production limitations, FDA restrictions, sale of our API businesses, and other factors.

Historically, we have been able to react effectively to situations that require alternate sourcing. Should such 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 (refer to 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. We also have manufacturing facilities in the U.K., Belgium, France, Germany, Austria, Israel, Mexico, and Australia, along with a joint venture in China (refer to 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.

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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 the following percentage of consolidated net sales:

Year Ended December 31, 2018	December 31, 2017	December 31, 2016
12.8%	13.0 %	13.0 %

Sales to Walmart are primarily in the CHCA segment. In addition, while no other customer individually comprises more than 10% of net sales, we do have other significant customers. The next five largest customers represent 23% of net sales in 2018. The loss of several of these customers could be material. We believe we generally have good relationships with all of our customers (refer to Item 1A. Risk Factors - Risks Related to Operations for risks associated with customers).

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 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 health and wellness 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;
- Diversity of thought, experience and perspective;
- Providing a safe and healthy work environment for our 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 (refer to 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 Rx, OTC drug products, API, and Infant Formula Foods. 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 products 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 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 approval of an ANDA or NDA prior to marketing. 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 non-prescription 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 these drugs generally requires less time and expense than the development process of a new drug, the size and duration of required studies can vary greatly. Prior to the onset of the Generic Drug User Fee Amendments of 2012 ("GDUFA"), the FDA approval of generic drug applications took approximately three to five times longer than approval of innovator drugs. Pursuant to GDUFA II, beginning October 1, 2017, year five of the program, the FDA pledged to complete a first cycle review on 90% of electronic generic applications within 10 months of submission.

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 another party 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.

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. needed to be completed by November 26, 2018, 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 formula manufacturing facilities have been inspected by the FDA with no corrective actions required.

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.

Active Pharmaceutical Ingredients

Third parties develop and manufacture API for use in certain of our products that are exported to the U.S. and other global markets. Before API can be commercialized in the U.S., the manufacturer and/or developer 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 or imported. For API

exported to European markets, the manufacturer must 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 European Union ("EU")-GMP and European Pharmacopeia standards.

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 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 U. S., 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, testosterone, midazolam, 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 laws regulating the manufacture and distribution of certain products.

Federal Healthcare Programs and Drug Pricing Regulation

Within the U.S., government healthcare insurance and welfare programs such as the Medicare and Medicaid programs are important third party payers for patients who take our products. These programs include several indirect forms of price regulation applicable to our drug products as a condition for coverage and/or payment for our products and also regulate the amount that pharmacies and other healthcare providers will be paid for our products. Specifically, 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 three government pricing program agreements: (i) a Medicaid rebate agreement with the Secretary of Health and Human Services ("HHS") 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; (ii) a 340B program agreement with the Secretary of HHS to provide discounts to certain "covered entity" safety net healthcare providers; and (iii) a Master Agreement with the Department of Veterans Affairs ("VA") under which discounts are available for purchases by federal agencies. We have such agreements in effect.

Medicaid Rebate Agreement

The Medicaid rebate agreement requires the drug manufacturer to remit rebates to each state Medicaid agency on a quarterly basis for both fee-for-service and Medicaid managed care organization utilization. Rebate amounts are based on pricing data reported by the manufacturer to the Centers for Medicare & Medicaid Services (“CMS”), including Average Manufacturer Price ("AMP") and, in the case of innovator products, Best Price ("BP"). 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.

Under the Medicaid rebate program, the minimum rebate amounts due are as follows: (i) for noninnovator products, in general generic drugs marketed under ANDAs, the rebate amount is 13% of the AMP for the quarter; and (ii) 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, but likewise generally applies where and to the extent that a manufacturer’s AMP increases faster than the rate of inflation.

CMS issued a final regulation, generally effective April 1, 2016, to implement changes to the Medicaid rebate program under the 2010 health reform legislation (“Health Reform Law”) and otherwise to provide program guidance. In addition to guidance concerning rebate program administration matters, the regulation also addressed certain related Medicaid reimbursement matters. First, under the Health Reform Law, CMS has also begun to use manufacturer AMP data to calculate reimbursement limits for pharmacies for multiple source drugs under the Medicaid program, known as the federal upper limits ("FULs"). 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. Second, the regulation also directed states to update their Medicaid payment methodologies to provide for payment amounts designed to reflect pharmacies’ "actual acquisition costs" for drugs, a change from the prior "estimated acquisition" standard. The regulation also required states to provide the government with findings to support their compliance with this standard by April 1, 2017.

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 within specified time frames. 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.

340B Program Agreement

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 certain hospitals that serve a disproportionate share of low-income patients.

Master Agreement with the Department of Veterans Affairs

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 to enter into a Master Agreement with the VA. Under the Master Agreement, the company must offer its innovator drugs for procurement under the Federal Supply Schedule ("FSS") contracting program, and must charge certain agencies (VA, Department of Defense, Public Health Service and the Coast Guard) no more than a statutory Federal Ceiling Price ("FCP"). The FCP is calculated based on Non-Federal Average Manufacturer Price data we submit to the VA. FSS contracts include extensive disclosure and certification requirements and standard government terms and conditions with which we must comply. Consistent with VA's interpretation of the Master Agreement, we have also entered into an agreement to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies.

Medicare Part D "Coverage Gap" Rebates

For certain innovator products, manufacturers must also enter into an agreement with the Secretary of HHS to provide rebates with respect to utilization of their products by certain Medicare Part D beneficiaries while those patients are within the Medicare Part D benefit "coverage gap." Manufacturers are not required to submit separate pricing data under this program; the rebate amount is calculated by CMS based on Part D plans' "negotiated prices" paid to pharmacies.

Other Price Regulation

In addition to these technical government pricing regulation programs, drug pricing has come under increasing public scrutiny arising out of general concerns about high drug costs or price increases, and transparency of pricing and discounting practices within the pharmaceutical distribution system. Several states, including Maryland, Nevada, and California, have recently enacted laws that prohibit "price gouging," require manufacturers to report certain information concerning price increases exceeding certain amounts, and/or provide advance notice of price increases to certain entities (refer to 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 federal, 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, legislation, regulation and laws that may impact our business include, but are not limited to:

- *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.

- *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")* - HIPAA is a set of regulations designed to protect personal information and data collected and stored in medical records. It established a national standard to be used in all doctors' offices, hospitals and other businesses where personal medical information is stored. In addition to protecting personal medical information, HIPAA also gives patients the right to view their medical records and request changes if the data is incorrect. 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 Eastern and Western Europe, Israel, Mexico, Australia, countries in Asia, South America, and the Middle East, 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 and cosmetics. Other regulatory agencies, organizations and legislation that may impact our business include, but are not limited to:

- *Privacy Regulations* - We are subject to numerous global laws and regulations designed to protect personal data, such as the European Union General Data Protection Regulation ("GDPR"). The GDPR introduced more stringent data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules. The GDPR increased our responsibility and potential liability in relation to personal data that we process, and we have put in place additional mechanisms to ensure compliance with the GDPR.

- *Transparency Laws* - In various jurisdictions in which we operate, we are subject to the laws and regulations aimed at increasing transparency of financial relationships between healthcare professionals and pharmaceutical/medical device manufacturers. These acts require certain pharmaceutical

manufacturers to engage in extensive tracking of payments or transfers of value to healthcare professionals.

- *Anti-Bribery Laws* - Various jurisdictions in which we operate have laws and regulations, including the U.K. Bribery Act 2010 and the Irish Criminal Justice (Corruption Offenses) Act 2018, aimed at preventing and penalizing corrupt and anticompetitive behavior.

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 EU, as well as many other locations around the world, the manufacture and sale of medicinal products are 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 regulation 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.
In 2011, it was first proposed that the EU Member States had to transition to the European Falsified Medicines Directive (the “Directive”). The Directive was subsequently written into national law on January 2, 2013. The Directive made reference to a Delegated Act (the Delegated Act lists the detailed requirements for manufacturers). The Delegated Act was finalized and published in February 2017, and given a two-year implementation period. 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. The requirements deriving from European pharmacovigilance regulation are constantly expanding due to increasing guidance on good vigilance practices and increased communication on inspectors' expectations. Pharmacovigilance fee regulation 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.

The wholesale distribution of medicinal products is an important activity in the integrated supply chain management. The quality and the integrity of medicinal products can be affected by a lack of adequate control. To this end, the EU Commission has published guidelines on Good Distribution Practice of medicinal products for human use in 2013. The present guidelines are based on Articles 84 and 85b(3) of medicinal products for human use directive.

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. On May 25, 2017, the EU's Medical Device Regulation (the "MDR") became effective. Beginning May 26, 2024, all medical devices sold in the EU will need to be approved under the MDR. Notified Bodies, which are organizations accredited by a member state, can continue to approve medical devices under the existing Medical Device Directives (the "MDDs") until May 26, 2020. Beginning on May 27, 2020, Notified Bodies will no longer be able to approve new medical devices under the MDDs or approve notifications of "substantial" design changes, including changes to labeling/packaging, changes to the manufacturing process, or the addition of new features and functionality, to medical devices that were approved under the MDDs.

Dietary Supplements

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, Nutritional & Health Claims Regulation (EC) No 1924/2006, the Foods Intended for Particular Nutritional Uses Directive 2009/39/EC, and 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, 2018, we had approximately 10,600 full-time and temporary employees worldwide, of which approximately 19% were covered by collective bargaining agreements. We consider our employee relations generally good.

Available Information

Our principal executive offices are located at The Sharp Building, Hogan Place, Dublin 2, D02 TY74, and our North American base of operations is 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-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 U.S. 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

We face vigorous competition from other pharmaceutical and consumer packaged goods 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 health and wellness products. Competition is also impacted by changes in regulations and government pricing programs that may give competitors an advantage. 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.

- As a manufacturer of generic versions of brand-name drugs through our CHCA 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 of potential market exclusivity.

- Our CHCA 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 and OTC pharmaceuticals 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 CHCA segment has seen an increase in direct to consumer advertising by several branded competitors, which may increase in the future, 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 CHCI 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.

- Our CHCA and RX segments also experience competition from generic manufacturers, some of whom are significantly larger than we are, who may develop their products more rapidly or complete regulatory approval processes sooner, or may market their products earlier than we do.

If we do not continue to 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 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.

- 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 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 regulated generic drug products in our CHCA and RX segments are bioequivalent to their branded counterparts, which may require bioequivalence studies, and in the case of topical products, even more extensive clinical endpoint trials to demonstrate their 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 may require re-design to meet evolving FDA standards, 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. Any of these events may negatively impact our net sales.

- Even if we are successful in developing a product, our customers' failure to launch one of our products successfully, or delays in manufacturing developed products, 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.

Our CHCA and CHCI 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.

Consumer preferences related to health and nutritional concerns may change, which could negatively impact demand for our CHCA and CHCI 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 CHCA 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 CHCA segment sales could be negatively impacted if consumers forgo obtaining healthcare or reduce their healthcare spending.

- Our CHCI segment's success is dependent on the continued growth in demand for its lifestyle products, which include weight management, pregnancy and fertility kits, sleep management, smoking cessation, and eye care. If demand for these products decreases, our CHCI segment's results of operations would be negatively impacted.

- Our CHCA 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 CHCA segment's results of operations.

- Our infant formula product category within our CHCA 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 operate in highly regulated industries, 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. Changes in existing regulations or the adoption of new regulations in the countries in which we operate could impose restrictions or delays on our ability to manufacture, distribute, sell or market our products, may be difficult or expensive for us to comply with, and may adversely affect our revenue, results of operations, and financial condition. 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 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 and/or possibly reducing our market share.

- 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. All marketing authorization holders in the EU member states and EEA

members Norway, Iceland, Liechtenstein and Switzerland were required to introduce the necessary changes by February 9, 2019 (or risk forfeiting their product licenses). However, manufacturers based out of Greece, Belgium and Italy have an extended timeline until February 9, 2025 to implement the serialization guidelines as they already feature similar requirements on their current drug packages. Compliance with the new U.S. and EU electronic pedigree requirements has and will continue to 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.

- 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.

- If we are unable to successfully obtain the necessary quota for controlled substances and List I chemicals, we risk having delayed product launches or failing 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.

- In order to commercially distribute our medical device products in the EU, they need to conform with the requirements of applicable EU directives. 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, which includes an audit of the manufacturer's quality system and, for some products, specific product testing. If our products fail to meet the applicable EU directives, then we may not meet our projected growth targets and/or incur fines and penalties.

- 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.

Continuing Healthcare reforms 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 some markets in the EU and 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. For example, the recently introduced Affordable Drug Manufacturing Act would create a U.S. federal agency tasked with manufacturing certain generic drugs to be offered directly to consumers. It is unclear if this proposed legislation will be enacted, but these or similar legislative or regulatory efforts could place further pricing pressure on our products and could negatively impact our results of operations.

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 Rebate Agreement, we have entered into various government drug pricing agreements with the U.S. government. There are inherent risks associated with participating in these programs, including the following:

- By their nature, these programs require us to provide discounts and rebates and therefore reduce our net product revenue. Further, because the amounts of these discounts are based on our commercial sales practices and can be adversely affected by both significant discounts and price increases, it is important that we maintain pricing practices that appropriately take into account these government pricing programs.

- 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 on a timely basis, 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.

- Because many of our products may be subject to Medicaid FULs or CMS’s new Medicaid “actual acquisition cost” payment methodology standard, our products may be subject to reimbursement pressures, and in some cases, those pressures may result from practices outside of our control, including how our competitors price their equivalent products. Based on our initial evaluation, we do not believe that the changes have had a material impact on our business. However, states are continuing to evaluate their payment methods, and we cannot predict how the new FUL or state payment methodologies will affect our pharmacy customers or to what extent these customers may seek additional discounts in light of reimbursement changes. We also cannot predict how the sharing of FUL data and retail survey prices may impact competition in the marketplace in the future.

- Under the 340B program, if we fail to provide required discounts to covered entities, we may be subject to refund claims or civil money penalties under that program.

- If we inadvertently overcharge the government in connection with our FSS contract or TriCare 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.

Perrigo Company plc - Item 1A
Risk Factors

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 the products mentioned above, 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 and harm to our reputation, 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.

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Changes in regulation could impact the supply of the 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 who 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, disruption or misuse of our information systems, cyber security efforts or personal data could have a material adverse effect on our business.

We are increasingly dependent upon information technology systems to operate our business. Our systems, information, and operations, as well as our independent vendor relationships (that support information technology and manufacturing infrastructure), are highly complex. These systems may contain confidential information (including trade secrets or other intellectual property or proprietary business information). The size and complexity of these systems makes them potentially 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 and address.

Cyber attacks have become increasingly common, and we experience phishing, firewall, business email compromise and other types of attacks on our information technology systems. While we continue to employ resources to monitor our systems and protect our infrastructure, including the use of outside advisors, these measures may prove insufficient depending upon the attack or threat posed, and that could subject us to significant risks, including, without limitation:

- Breaches or disruptions that impair our ability to develop, meet regulatory approval efforts, 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, that damages our reputation and causes us to lose customers, experience lower sales volume, and incur significant liabilities;
- Incurring significant expense to ensure compliance with any required disclosures mandated by the numerous global privacy and security laws and regulations; and
- Any interruption, security breach, or loss, misappropriation, or unauthorized access, use or disclosure of confidential information could result in financial, legal, business, or reputational harm to us and could have a material adverse effect on our business, financial condition, and results of operations.

We are also subject to numerous laws and regulations designed to protect personal data, such as the national laws implementing the GDPR. The GDPR introduced more stringent data protection requirements

in the EU, as well as significant fines for breaches of the data protection rules. The GDPR increased our responsibility and liability in relation to personal data that we process, and we have put in place additional mechanisms to ensure compliance with the new EU data protection rules.

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 12.8% of our net sales for the year ended December 31, 2018. While no other customer individually comprised more than 10% of net sales, we do have other significant customers. If our relationship with Walmart or any of our other significant customers, including the terms of doing business with the customers, changes significantly, it could have a material adverse impact on us (refer to Item 1. Business - Significant Customers).

Many of our customers, which include major global, national, and regional retail drug, supermarket, and mass merchandise chains, major wholesalers, sourcing groups, hospitals, pharmacies, and drug, and grocery stores located primarily in Europe, 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.

Although we have divested our rights to the Tysabri® royalty stream, we are entitled to additional milestone payments if certain specified thresholds are met, and any negative developments related to Tysabri® could have a material adverse effect on our receipt of those payments.

During the year ended December 31, 2017, we divested our rights to the Tysabri® royalty stream to Royalty Pharma for $2.2 billion in cash at closing and up to $250.0 million and $400.0 million in milestone payments. During the year ended December 31, 2018, Tysabri® met the 2018 global net sales threshold resulting in a $170.1 million gain recorded in Change in financial assets. We received the $250.0 million royalty payment on February 22, 2019. In order for us to receive the 2020 milestone payment, Royalty Pharma contingent payments for Tysabri® sales in 2020 must exceed $351.0 million. The fair value of the 2020 milestone payment is $73.2 million as of December 31, 2018. Our receipt of the 2020 milestone payment may be negatively impacted if the royalty streams decrease and are insufficient to meet the specified thresholds. Given the fact that the 2020 milestone payment is recorded at fair value, if it is determined that Tysabri® global sales levels do not meet specific thresholds, we would recognize a material charge in the Consolidated Statement of Operations. Factors that may have an adverse effect on the Tysabri® royalty stream include:

- 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 its market share. In February 2016, a competitor's pipeline product, Ocrevus®, received breakthrough therapy designation from the FDA, and this product was launched in 2017. The product is expected to compete with Tysabri® and have a significant negative impact on the Tysabri® royalty stream;

Biogen is the owner of the patents on Tysabri®. The loss of protection of these patents, such as a patent invalidation, could adversely affect the royalty stream from Tysabri®. In addition, once the Tysabri® patents expire, other generic companies may introduce products similar to Tysabri® that could adversely affect the royalty stream;

- Foreign currency movement, which could have a negative impact on Biogen's Tysabri® sales, thereby reducing the royalties;

- 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 royalty revenue 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®.

Furthermore, there can be no assurance that Royalty Pharma will pay the 2020 milestone payment even if the specified thresholds are met.

We are dependent on the services of certain key members of management. Our inability to successfully manage transition, or the failure to attract and retain other key members of management, 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. 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.

Management transition creates uncertainties, and any difficulties we experience in managing such transitions may negatively impact our business.

Over the last several years, we have experienced a number of changes in our executive leadership. Most recently, on October 8, 2018, we announced the appointment of Murray S. Kessler as President and Chief Executive Officer and member of our Board. Mr. Kessler’s appointment followed the resignation of Uwe Roehrhoff, who had held those roles since his appointment in January 2018. Changes in executive management create uncertainty. Moreover, changes in our company as a result of management transition could have a disruptive impact on our ability to implement, or result in changes to, our strategy and could negatively impact our business, financial condition and results of operations.

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 Pharma Invest N.V. ("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 CHCI 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 CHCI 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.

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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.

Perrigo Company plc - Item 1A
Risk Factors

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.

Some of the factors that may impact our quarterly results include the severity, length and timing of the cough/cold/flu and allergy seasons, the 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, changes in the levels of inventories maintained by our customers, and the timing of retailer promotional programs. These and other factors may result in significant variations in our operating results from quarter to quarter.

We may not be able to sustain or improve operating results in our business segments.

- We continue to experience a significant year-over-year reduction in pricing in our RX segment due to competitive pressures. This softness in pricing is attributable to various factors, including increased focus from customers to capture supply chain productivity savings, competition in specific products, and consolidation of certain customers. While in the fourth quarter of 2018, we experienced a year-over-year decrease in pricing pressure, we expect softness in pricing to continue to impact the segment for the foreseeable future.

- The CHCI segment has been positively impacted by market dynamics in countries such as the Nordics, Italy, and Portugal offset by softness in certain brand categories in France and Germany, as well as by unfavorable foreign currency impacts primarily in the U.K. related to Brexit. The CHCI segment has restructured its approach to addressing these markets including by: (1) implementing of a brand prioritization strategy to address these market dynamics, with an objective to balance the cost of advertising and promotional investments with expected contributions from category sales, and (2) restructuring its sales force in each of these markets to more effectively serve customers. The combination of these actions is expected to improve the segment's focus on higher value OTC products, reduce selling costs and improve operating margins in the segment.

- We continue to experience a reduction in pricing expectations within our CHCA segment, primarily in the cough/cold, animal health, and analgesics categories due to various factors, including focus from customers to capture supply chain productivity savings and competition in specific product categories. We expect this pricing environment to continue to impact our CHCA segment for the foreseeable future.

There can be no assurance that we will not continue to experience challenges related to our segments, and these challenges could have a material impact on our business, cash flows, and results of operations or result in impairment charges, and the market value of our ordinary shares and/or debt securities may decline.

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.

In the normal course of business, we engage in discussions relating to possible acquisitions and divestitures. These transactions are accompanied by a number of risks. Many of these risks are beyond our control, and any one of them could result in increased cost, 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.

Acquisitions

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:

- Difficulty involved with managing the expanded operations of the respective parties, as well as identifying the extent of all weaknesses, risks, and contingent and other liabilities;
- Uncertainties involved in assessing the value, strengths, and potential profitability of the respective parties, as well as identifying the extent of all weaknesses, risks, and contingent and other liabilities of acquisition

targets;
- Unanticipated changes in the business, industry, market or general economic conditions different from the assumptions underlying our rationale for pursuing the transaction;
- Difficulties due to a lack of, or limited experience in, any new product or geographic markets we enter;
- 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 that may detract attention from our day-to-day business, and substantial costs associated with the transaction process or other material adverse effects as a result of these integration efforts; and
- Difficulties, restrictions or increased costs associated with raising future capital in connection with an acquisition may impact our liquidity, credit ratings and financial position, thereby making it more difficult, restrictive or expensive to raise future capital. In addition, the issuance of equity to pay a portion of the purchase price for an acquisition would dilute our existing shareholders.

Divestitures

We may evaluate potential divestiture opportunities with respect to portions of our business (including specific assets or categories of assets) from time to time, and may proceed with a divestiture opportunity if and when we believe it is consistent with our business strategy and initiatives. Any future divestitures could expose us to significant risk, including without limitation:

- Our ability to effectively transfer liabilities, contracts, facilities and personnel to any purchaser;
- Fees for legal and transaction-related services;
- Diversion of management resources; and
- Loss of key personnel and reduction in revenue.

If we do not realize the expected strategic, economic or other benefits of any divestiture transaction, it could adversely affect our financial condition and results of operations.

The plan to separate our RX business is contingent upon a number of conditions, is subject to change in form or timing, may not achieve the intended benefits, and could adversely affect our business and financial condition.

On August 9, 2018, we announced a plan to separate our RX business which, when completed, will enable us to focus on expanding our consumer-focused businesses. We have begun the preparations for the separation, which may include a possible sale, spin-off, merger or other form of separation. While we are currently targeting to complete the separation by the end of 2019, the form of separation may delay the completion of the separation beyond this date, however, there can be no assurances as to the form or timing of a separation or if a separation will be consummated.

The proposed separation, regardless of form, will be a complex endeavor and could be affected by unanticipated developments and other factors, such as the impact of the U.S. Tax Cuts and Jobs Act ("U.S. Tax Act"), other tax reform and related existing or future regulations (which may be retroactive), the potential impact of the NoA issued by Irish Revenue on our financial condition, existing interdependencies with our manufacturing and shared-service operations, the outcome of the price-fixing claims brought

against us, results of other strategic initiatives, and changes in market conditions, any of which could change, delay or prevent the achievement of the strategic and financial objectives of the separation. In addition, the separation of the RX business could impact our ability to retain key employees, comply with existing debt arrangements, maintain our credit ratings and raise future capital.

Even if the separation is completed, we may not achieve the anticipated operational, financial, strategic or other benefits of the separation. After the separation, the combined value and financial performance of the

Company and RX business may not equal the value and financial performance of the Company had the separation not occurred.

In connection with the proposed separation, we anticipate incurring significant preparation costs, excluding restructuring expenses and transaction costs, in the range of $45.0 million to $80.0 million depending on the final structure of a transaction, with a spin-off resulting in costs at the higher end of this range. In addition, completion of the separation will require a significant amount of management time and effort, which may disrupt our business or otherwise divert management's attention from other aspects of our business, including our other strategic initiatives, possible organic or inorganic growth opportunities, and customer and vendor relationships. Any of the foregoing risks could adversely affect our business, results of operations, liquidity, and financial condition.

Our business could be negatively affected by the performance of our collaboration partners and suppliers.

We have entered into strategic alliances with partners and suppliers to develop, manufacture, market and/or distribute certain products, or components of our products in various markets. We commit substantial effort, funds and other resources to these various collaborations. There is a risk that our investments in these collaborative arrangements will not generate financial returns. While we believe our relationships with our partners and suppliers generally are successful, disputes, conflicting priorities or regulatory or legal intervention could be a source of delay or uncertainty as to the expected benefit of the collaboration (refer to Item 8. Note 17). A failure or inability of our partners or suppliers to fulfill their collaboration obligations, or the occurrence of any of the risks above, could have an adverse effect on our business, financial condition 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 goodwill and intangible assets on our balance sheet as a result of previous acquisitions, which could become impaired and lead to material charges in the future.

As of the year ended December 31, 2018, we recorded goodwill, definite-lived and indefinite-lived intangible asset impairment charges of $136.7 million, $49.6 million and $27.7 million primarily in our CHCA segment, respectively, and $8.7 million of impairment charge related to certain In-process research & development ("IPR&D") assets in our CHCA segment.

As of the year ended December 31, 2017, we recorded definite-lived intangible asset impairment charges of $19.7 million related to developed product technology/formulation and product rights, and distribution and license agreements primarily in our RX segment and $12.7 million of impairment charge related to certain IPR&D assets primarily in our RX segment.

As of the year ended December 31, 2016, we recorded goodwill impairment charges of $1.1 billion related to our Specialty Sciences, Branded Consumer Healthcare-Rest of World, BCH-Belgium, and Animal Health reporting units and indefinite-lived and definite-lived intangible asset impairment charges of $1.5 billion related to trademarks, trade names and brands, developed product technology/formulation and product rights, distribution and license agreements, and supply agreements.

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. Goodwill, indefinite-lived intangible asset, and definite-lived intangible asset impairments are recorded in Impairment charges on the Consolidated Statement of Operations. As of December 31, 2018, the net book value of our goodwill and intangible assets were $4.0 billion and $2.9 billion, respectively (refer to Item 8. Note 4).

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, making key executive employee changes, performing a strategic portfolio review, and disposing of certain assets. Furthermore, we have developed a new vision for the Company as we transition into a consumer-focused company. We believe these initiatives will enhance our net sales, 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.

While we have remediated previously identified material weaknesses in our internal control over financial reporting related to our income tax process, we may identify other material weaknesses in the future.

We are required to evaluate the effectiveness of our disclosure controls on a periodic basis and publicly disclose the results of these evaluations and related matters in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. During the years ended December 31, 2016 and December 31, 2017, we identified certain material weaknesses in our internal control over financial reporting that related to the matters associated with our income tax process, which have been remediated.

While we have remediated those previously identified material weaknesses, there can be no assurances that our controls will remain adequate. Any failure to implement or maintain required new or improved controls, or any difficulties we encounter in their implementation, including retention of key employees, could result in additional material weaknesses or material misstatements in our Consolidated Financial Statements. Any new misstatement could cause us to fail to meet our reporting obligations, reduce our ability to obtain financing or cause investors to lose confidence in our reported financial information, leading to a decline in our stock price. We cannot assure you that we will not discover additional weaknesses in our internal control over financial reporting.

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;
- Changes to U.S. and foreign trade policies, including the enactment of tariffs on goods imported into the U.S., including but not limited to, goods imported from Mexico; 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 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, the Irish Criminal Justice (Corruption Offenses) Act 2018, and similar laws.

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 and supply partners 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 involves the following risks:

- 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.

- 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. 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. Also, further threats of armed hostilities in certain countries 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.

- The UK held a referendum on June 23, 2016 on its membership in the EU. A majority of UK voters voted to exit the EU (“Brexit”). The UK is scheduled to leave the EU on March 29, 2019, and negotiations are taking place to determine the future terms of the UK’s relationship with the EU, including the terms of withdrawal, the terms of future trading and relations and any potential transition periods. Brexit has created significant instability and volatility in the global financial markets, has led to significant weakening of the British pound compared to the U.S. dollar and other currencies, and could adversely affect European or worldwide economic or market conditions. Although it is unknown what the future trading terms with the EU will be, they may impair the ability of our operations in the EU to transact business in the future in the UK, and similarly the ability of our UK operations to transact business in the future in the EU. Specifically, it is possible that there will be greater restrictions on imports and exports between the UK and EU countries, increased restrictions on freedom of movement for employees, and increased regulatory complexities. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace or replicate. We are actively monitoring Brexit updates from a government and regulatory perspective. We are preparing for a “hard (no deal) Brexit," which is intended to ensure we meet both applicable EU and UK regulatory requirements as well as stock-builds to secure supply continuity. There can be no assurances, however, that these preparations will be sufficient or that

the final exit terms will be as we anticipate. Any of the above mentioned effects of Brexit, and others we cannot anticipate, could adversely affect our business, business opportunities, operations, and financial results.

- 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, or decrease the value of our assets.

- The challenging economic conditions have also impacted the movements in exchange rates, which have experienced significant recent volatility. Uncertainty regarding the future growth rates between countries, the influence of central bank actions, and the changing political environment globally may contribute to continued high levels of exchange rate volatility, which could have an adverse impact on our results.

- Our customers could be adversely impacted if U.S. economic conditions worsen. Our CHCA 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. Approximately 35% of Omega’s sales are in other foreign currencies, with the majority of the product costs for these markets denominated in euros.

In addition, 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 continue to experience 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. 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.

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 a wide variety of commercial, manufacturing, development, marketing, sales and other business-related matters, including, but not limited to, competitive issues, pricing, contract issues, intellectual property matters, false advertising, unfair competition, taxation matters, workers' compensation, product quality/recall, environmental remediation, securities law, disclosure, and regulatory issues. Litigation is unpredictable and can be costly. We intend to vigorously defend against any lawsuits, however, we cannot predict how the cases will be resolved. Adverse results in the cases could result in substantial monetary judgments. 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 (refer to Item 8. Note 16).

- 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 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 CHCI 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.

- Additionally, we may be the target of claims asserting violations of securities fraud and derivative actions, or other litigation proceedings in the future.

Increased scrutiny on pricing practices and competition in the pharmaceutical industry, including antitrust enforcement activity by government agencies and class action litigation, may have an adverse impact on our business and results of operations.

There has been increased scrutiny regarding sales, marketing, and pricing practices in the pharmaceutical industry from both government agencies and the media, including allegations of “price gouging” and/or collusion. This includes recent U.S. Congressional inquiries and hearings in connection with the investigation of specific price increases by several pharmaceutical companies, proposed and enacted legislation seeking greater transparency in drug pricing, and criminal investigations regarding drug pricing. U.S. federal and state prosecutors have issued subpoenas to a number of pharmaceutical companies seeking information about their drug pricing practices, and several class action lawsuits have been filed that allege price-fixing with respect to various pharmaceutical products. In December 2016, the Antitrust Division of the U.S. Department of Justice (the “Antitrust Division”) filed criminal charges against two former executives from a competitor of the Company for their roles in conspiracies to fix prices, rig bids and allocate customers for certain generic drugs.

On May 2, 2017, we disclosed that search warrants were executed at a number of Perrigo facilities and other locations in connection with the Antitrust Division’s ongoing investigation related to drug pricing in the pharmaceutical industry. Although no charges have been brought to date against Perrigo or any of our current employees (or, to the best of our knowledge, former employees), we take the investigation very seriously.

If criminal antitrust charges are filed involving Perrigo, we would incur substantial litigation and other costs, and could face substantial monetary penalties, injunctive relief, negative publicity and damage to our reputation. Regardless of the ultimate outcome, responding to those charges would divert management’s time and attention and could impair our operations. Further, we cannot predict whether legislative or regulatory changes may result from the ongoing public scrutiny of our industry, what the nature of any such changes might be, or what impact they may have on Perrigo. Any of these developments could have a material adverse impact on our business, results of operations, and reputation. While we intend to defend

these lawsuits vigorously, any adverse decision could have a material adverse impact on our business, results of operations and reputation.

We are cooperating with the government's investigation and are committed to operating our business in compliance with all applicable laws and regulations and the highest standards of ethical conduct. We do not condone, and will not countenance, any violation of these standards by our employees, agents, and business partners.

In addition, we have been named as a co-defendant with certain other generic pharmaceutical manufacturers in a number of class action lawsuits alleging that we and other manufacturers of the same product engaged in anti-competitive behavior to fix or raise the prices of certain drugs starting, in some instances, as early

as June 2013 (refer to Item 8. Note 16). While we intend to defend these lawsuits vigorously, any adverse decision could have a material adverse impact on our business, results of operations and reputation.

Publishing earnings guidance subjects us to risks, including increased stock volatility, that could lead to potential lawsuits by investors.

Because we publish earnings guidance, we are subject to a number of risks. Actual results may vary from the guidance we provide investors from time to time, such that our stock price may decline following, among other things, any earnings release or guidance that does not meet market expectations.

It has become increasingly commonplace for investors to file lawsuits against companies following a rapid decrease in market capitalization. We have been in the past, and may be in the future, named in these types of lawsuits. These types of lawsuits can be costly and divert management attention and other resources away from our business, regardless of their merits, and could result in adverse settlements or judgments, which could have a material impact on the Company.

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 CHCA, CHCI, 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 CHCA or RX segments may seek approval to market drug 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. 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.

- 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, 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;
- Insurance may not be available to us at an economically reasonable cost or our insurance may not adequately cover our liability in connection with claims brought against us; and
- As our business inherently exposes us to claims, 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. An unfavorable determination on Perrigo Company plc's treatment as a foreign corporation under section 7874 of the Code could have a material impact on our consolidated financial statements in future periods.

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 (refer to Item 8, Note 14).

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.

Since our acquisition of Elan in 2013, the United States Treasury ("Treasury") and the IRS have issued a number of Notices and proposed, temporary, and final regulations, including most recently, on July 12, 2018, new final regulations addressing various aspects of section 7874 and related provisions, including guidance to address certain specific post-inversion transactions. All of the Notices and regulations are either effective for dates after the Elan acquisition occurred or do not provide guidance that we believe would have a material impact on the treatment of our status as a foreign corporation.

The Organization for Economic Co-operation and Development ("OECD"), which represents a coalition of member countries, has recommended changes to numerous long-standing tax principles relating to Base Erosion and Profit Shifting ("BEPS"). These changes are being adopted and implemented by many of the countries in which we do business and may increase our taxes in these countries. In addition, the European Commission has launched several initiatives to implement BEPS actions including an Anti-Tax Avoidance Directive ("ATAD") and having a common (consolidated) corporate tax base. It is unclear at present if and how these initiatives will be implemented by the EU countries. Specifically, Ireland has implemented so-called "controlled foreign corporation legislation" effective January 1, 2019 as required by the ATAD measures. Ireland has embarked on a consultation process to further implement the ATAD I & II directives and BEPS related measures. Other EU countries have implemented or are contemplating tax legislation to implement BEPS actions, similar to the Ireland legislation, including tax legislation enacted by the French parliament in December 2018. The shape and implementation of this reform may adversely impact our

consolidated effective tax rate. The recent announcement from the OECD Inclusive Framework group that they plan to develop further proposals to the existing international tax rules that could go beyond the so-called arm's length principle may further adversely impact our consolidated effective tax rate.

On December 22, 2017, the U.S. enacted the U.S. Tax Act. The U.S. Tax Act includes a number of significant changes to existing U.S. tax laws that impact us. These changes include a corporate income tax rate reduction from 35% to 21%, full expensing of fixed assets placed in service in 2018 and the elimination or reduction of certain U.S. deductions and credits, including limitations on the deductibility of interest expense and executive compensation. The U.S. Tax Act also transitions international taxation from a worldwide system to a modified territorial system. This modified territorial system includes, among other items, base erosion prevention measures

which have the effect of subjecting certain earnings of our U.S. owned foreign corporations to U.S. taxation as global intangible low-taxed income ("GILTI") and the establishment of a minimum tax on certain payments from our U.S. subsidiaries to related foreign persons as base erosion and anti-abuse tax ("BEAT"). These changes became effective in 2018. The U.S. Tax Act also includes a one-time mandatory deemed repatriation tax on accumulated U.S. owned foreign corporations' previously untaxed foreign earnings ("Transition Toll Tax"). The Transition Toll Tax can be paid over an eight-year period starting in 2018 and will not accrue interest. Based on the 2017 U.S. federal income tax return filed by the Company, the Transition Toll Tax was paid in full with the 2017 U.S. federal income tax return. During 2018, Treasury and the IRS issued various forms of guidance, including notices of proposed rule making and proposed Treasury regulations, implementing and clarifying aspects of the U.S. Tax Act and other related topics, such as:

- Transition Toll Tax;
- BEAT;
- GILTI;
- Foreign tax credit computations;
- The full expensing of fixed assets placed in service in 2018;
- Interest expense limitations under Section 163(j);
- Deductibility of interest and/or royalty payments made by U.S. corporate taxpayers to foreign related parties in so-called "hybrid mismatch" arrangements under Section 267A; and
- The limitation of deductions for key executive compensation as determined under Section 162(m).

During the year ended December 31, 2018, we considered and evaluated Treasury and IRS guidance issued as described above and reflected certain changes in our income tax provision for 2018. In 2019, Treasury and the IRS are expected to issue final tax regulations ("Final Regulations") on certain code sections that were introduced by, or changed as a result of, the U.S. Tax Act. We will record the tax effects of the Final Regulations in the quarter in which they are issued.

Our preliminary estimate of the impact of the U.S. Tax Act (including the Transition Toll Tax) was recorded as of December 31, 2017 and was subject to the finalization of management's analysis related to certain matters, such as developing interpretations of the provisions of the U.S. Tax Act, changes to certain estimates and amounts related to the earnings and profits of certain U.S. owned foreign subsidiaries and the filing of our tax returns. U.S. Treasury regulations, administrative interpretations or court decisions interpreting the U.S. Tax Act required further adjustments and changes in our 2017 estimates, which did not have a material adverse effect on our business, results of operations or financial conditions. The final determination of the impact of the U.S. Tax Act (including the Transition Toll Tax) was completed in 2018, as required by SAB 118 (refer to Item 8, Note 14).

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

Our effective tax rate or cash tax payment requirements 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 rate or cash tax payment requirements, which may impact our future results and cash flows from operations (refer to Item 8, Note 14). These factors include, but are not limited to:

- Changes to tax laws or the interpretation of such tax laws (including additional proposals for fundamental international tax reform in a number of jurisdictions globally);
- 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, treatment or characterization of intercompany transactions, changes in available tax credits, grants and other incentives;
- Changes in stock-based compensation expense;
- Changes in U.S. generally accepted accounting principles;
- Expiration or the inability to renew tax rulings or tax holiday incentives; and
- Divestitures of current operations.

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 or 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 and in future periods after the determination. In addition, future period earnings may be adversely impacted by litigation costs, settlements, penalties or interest assessments.

We are currently involved in several audit and adjustment related disputes, including litigation, with the IRS. These include litigation regarding our 2009, 2010, 2011, and 2012 tax years, as well as proposed audit adjustments related to litigation costs and transfer pricing positions related to Athena Neurosciences, Inc. (“Athena”), a subsidiary of Elan acquired in 1996, for the 2011, 2012 and 2013 tax years.

In addition, on October 31, 2018, we received an audit finding letter from Irish Revenue for the years under audit 2012-2013. The audit finding letter relates to the tax treatment of the 2013 sale of the Tysabri® intellectual property and other assets related to Tysabri® to Biogen Idec from Elan Pharma. The consideration paid by Biogen to Elan Pharma took the form of an upfront payment and future contingent royalty payments. Irish Revenue issued a NoA on November 29, 2018 which assesses an Irish corporation tax liability against Elan Pharma in the amount of €1,636 million, not including interest or any applicable penalties. We disagree with this assessment and believe that the NoA is without merit and incorrect as a matter of law. We filed an appeal of the NoA on December 27, 2018 and will pursue all available administrative and judicial avenues as may be necessary or appropriate. As part of this strategy to pursue all available administrative and judicial avenues, Elan Pharma was, on February 25, 2019, granted leave by the Irish High Court to seek judicial review of the issuance of the NoA. The judicial review filing is based on our belief that Elan Pharma's legitimate expectations as a taxpayer have been breached, not on the merits of the NoA itself. If Perrigo is ultimately successful in the judicial review proceedings, the NoA will be invalidated and Irish Revenue will not be able to re-issue the NoA. The proceedings before the Tax Appeals Commission has been stayed until a decision on the judicial review application has been made, which could take up to, or more than, a year. No payment of any amount related to this assessment is required to be made, if at all, until all applicable proceedings have been completed, which could take a number of years. However, while we believe our position to be correct, there can be no assurance of an ultimate favorable outcome, and if the matter is ultimately resolved unfavorably it would have a material adverse impact on Perrigo, including on liquidity and capital resources. In addition, going forward, uncertainty regarding the future outcome of the NoA may have an adverse impact on our financial condition and strategy, including our plan to separate our Rx business.

At this time, we cannot predict the outcome of any audit or related litigation. Unfavorable developments in or resolutions of matters such as those discussed above could, individually or in the aggregate, have a

material impact on our consolidated financial statements in future periods (refer to Item 8, Note 14 for further information related to uncertain tax positions and ongoing tax audits and Item 8. Note 16 for further information related to legal proceedings).

Perrigo Company plc - Item 1A
Risk Factors

Risks Related to Capital and Liquidity

Our indebtedness could adversely affect our ability to implement our strategic initiatives.

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, 2018, our total indebtedness outstanding was $3.2 billion.

- 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.

- 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.

- 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.

- 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 (refer to 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 announced share repurchase plan or that our share repurchase plan will enhance long-term shareholder value.
In October 2015, the Board of Directors approved a three-year share repurchase plan of up to $2.0 billion (the "2015 Authorization"). Following the expiration of our 2015 Authorization, in October 2018, our Board of Directors authorized up to $1.0 billion of share repurchases with no expiration date (the "2018 Authorization"), subject to the Board of Directors’ approval of the pricing parameters and amount that may be repurchased under each specific share repurchase program. Through December 31, 2018, we repurchased a total of 7.8 million ordinary shares through the 2015 Authorization. The specific timing and amount of buybacks under the 2018 Authorization, if any, will depend upon several factors, including market and business conditions, the trading price of our ordinary shares, the nature of other investment opportunities and the availability of distributable reserves of Perrigo Company plc. 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 either in our articles of association or by way of a special resolution. Such disapplication of these preemption rights can either be generally applicable or be in respect of a particular allotment of shares.

At our annual general meeting of shareholders in May 2018, our shareholders authorized our Board of Directors to issue up to a maximum of 33% of our issued ordinary capital on that date for a period of 18 months from the passing of the resolution. At the annual general meeting, our shareholders also authorized our Board of Directors to issue ordinary shares on a nonpreemptive basis in the following circumstances: (i) an issuance of shares in connection with any rights issuance and (ii) an issuance of shares for cash, if the issuance is limited to up to 5% of the Company's issued ordinary share capital (with the possibility of issuing an additional 5% of the Company's issued ordinary share capital provided the Company uses it only in connection with an acquisition or a specified capital investment that is announced contemporaneously with the issuance, or which has taken place in the preceding six-month period and is disclosed in the announcement of the issuance), bringing the total acceptable limit to 10% of the Company's issued ordinary share capital. Once these authorizations expire, we cannot provide any assurance that they will be renewed by the shareholders at subsequent annual general meetings, 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, Irish income 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 (i) for a definite sum, (ii) provided by a court of competent jurisdiction and (iii) final and conclusive. An Irish High 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 High 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 High Courts if deemed to be contrary to public policy in Ireland.

- 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.

Irish law differs from the laws in effect in the U.S. with respect to defending unwanted takeover proposals and may give our Board of Directors less ability to control negotiations with hostile offerors.

We are subject to the Irish Takeover Panel Act, 1997, Takeover Rules, 2013. Under those Irish Takeover Rules, the Board of Directors is not permitted to take any action that might frustrate an offer for our ordinary shares once the Board of Directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (i) the issuance of ordinary shares, options or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business, or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which the Board of Directors has reason to believe an offer is or may be imminent. These provisions may give the Board of Directors less ability to control negotiations with hostile offerors and protect the interests of holders of ordinary shares than would be the case for a corporation incorporated in a jurisdiction of the United States.

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

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

- Our ability to receive cash dividends and distributions from our subsidiaries;
- Compliance with applicable laws and debt covenants;
- Our financial condition, results of operations, capital requirements, general business conditions, and other factors that our Board of Directors may deem relevant; and
- The availability of Perrigo Company plc's distributable reserves, being profits of the company available for distribution to shareholders.

Under Irish law, distributable reserves means the accumulated realized profits so far as not previously utilized by distribution or capitalization, less accumulated realized losses so far as not previously written off in a reduction or a reorganization of capital duly made. In addition, no distribution or dividend may be made if, at that time, Perrigo Company plc's's net assets are not, or would not be after giving effect to such distribution or dividend, equal to, or in excess of, the aggregate of Perrigo Company plc's called-up share capital plus undistributable reserves.
While we currently expect to continue paying dividends and operating our share repurchase plan, significant changes in our business or financial condition such as asset impairments, sustained operating losses and the selling of assets, could impact the amount of distributable reserves available to us. We could seek to create additional distributable reserves through a reduction in Perrigo Company plc's share premium, which would require 75% shareholder approval and the approval of the Irish High Court. The Irish High Court’s approval is a matter for the discretion of the court, and there can be no assurances that such approval would be obtained. In the event that additional distributable reserves are not created in this way, dividends, share repurchases or other distributions would generally not be permitted under Irish law until such time as Perrigo Company plc has created sufficient distributable reserves in our audited statutory financial statements as a result of its business activities.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our world headquarters is located in Dublin, Ireland, and our North American base of operations is located in Allegan, Michigan. We manufacture products at 20 worldwide locations and have R&D, logistics, and office support facilities in many of the regions in which we operate. We own approximately 74% of our facilities and lease the remainder. Our primary facilities by geographic area were as follows at December 31, 2018:

Country	Number of Facilities	Segment(s) Supported
Ireland	1	CHCA, CHCI, RX
United States	45	CHCA, CHCI, RX
Mexico	10	CHCA
United Kingdom	7	CHCI
France	5	CHCI
Belgium	4	CHCI
Austria	4	CHCI
Australia	4	CHCI
Israel	3	CHCA, CHCI, RX
India	2	CHCA, CHCI
Germany	1	CHCI

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 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.

Perrigo Company plc - Additional Item
Executive Officers

ADDITIONAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers and their ages and positions as of February 22, 2019 were:

	Title and Business Experience	Age
Svend Andersen	Mr. Andersen was named Executive Vice President and President, Consumer Healthcare International in February 2017. Prior to joining Perrigo in May 2016, Mr. Andersen served as Executive Vice President - Europe for LEO-Pharma from December 2015 to May 2016. Prior to that, he was Regional President and Corporate officer at Hospira, Inc.'s Europe, Middle East and Africa ("EMEA") business for five years, was Executive Vice President responsible for the Western European division's pharmaceuticals, generics, OTC and hospital products businesses at Actavis from 2008 to 2015 including leading Alpharma's EMEA businesses prior to its acquisition by Actavis, and prior to that, spent 10 years with Ferrosan (A Novo Nordisk Subsidiary) specialized in OTC and consumer health products as Vice President for Global Commercial Operations.	57
James E. Dillard III	James E. Dillard III was named Executive Vice President and Chief Scientific Officer in January 2019. Mr. Dillard joined Perrigo from Altria Group, Inc., where he served as Senior Vice President, Research, Development and Sciences and Chief Innovation Officer from January 2009 to May 2018. During his tenure with Altria Group, Mr. Dillard led the creation of the Regulatory Affairs function in 2009 and also served as Chief Innovation Officer for Altria Client Services and Senior Vice President of Research, Development & Regulatory Affairs for Altria Group. He held science and technology leadership roles with U.S. Smokeless Tobacco Company, an Altria Group Inc. operating company, from 2001 to 2009. Mr. Dillard worked for the U.S. Food and Drug Administration between 1987 and 2001 as Director of the Division of Cardiovascular and Respiratory Devices, as well as in various leadership roles in the Center for Devices and Radiological Health and the Office of Device Evaluation.	55
Thomas M. Farrington	Mr. Farrington was named Executive Vice President and Chief Information Officer in November 2015. He formerly served as Senior Vice President and Chief Information Officer from October 2006 to November 2015.	61
Ronald Janish	Mr. Janish was named Executive Vice President of Global Operations and Supply Chain in October 2015. He served as Senior Vice President of International and Rx Operations from 2012 until 2015 and as Managing Director of Perrigo's Australian operations from 2010 to 2012. Previously, he held Senior Vice President roles for Perrigo in International Market Development, China Business Development and Global Procurement.	53
Murray S. Kessler	Mr. Kessler was appointed President, Chief Executive Officer and Board Member of Perrigo Company plc, effective October 8, 2018. Before joining Perrigo, Mr. Kessler served as the Chairman of the Board of Directors, President and CEO of Lorillard, Inc. (2010-2015). He served as Vice Chair of Altria, Inc. (2009) and President and CEO of UST, Inc. (2000-2009), a wholly owned subsidiary. Previous to his time at UST, Mr. Kessler had over 18 years of consumer packaged goods experience with companies including Vlasic Foods International, Campbell Soup and The Clorox Company. Since 2015, Mr. Kessler has served as voluntary President of the United States Equestrian Federation, a non-profit national governing body.	59
Todd W. Kingma	Mr. Kingma was named Executive Vice President, General Counsel and Secretary in May 2006. He served as Vice President, General Counsel and Secretary from August 2003 to May 2006.	59
Sharon Kochan	Mr. Kochan was named Executive Vice President and President, RX Pharmaceuticals in October 2018. He served as Executive Vice President and President, Branded Consumer Healthcare International from February 2017 to October 2018. He served as Executive Vice President and General Manager, Consumer Healthcare International from August 2012 to February 2017. 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 March 2005 to March 2007. Mr. Kochan was Vice President, Business Development of Agis Industries (1983) Ltd. from July 2001 until the acquisition of Agis by the Company in March 2005.	50
James R. Michaud	Mr. Michaud was named Executive Vice President, Chief Human Resources Officer in August 2016. In 2014, Mr. Michaud was President of Human Resources Strategies, a consulting company focused on providing business based human resource strategies to a wide variety of companies in multiple industries. His corporate career spanned senior human resource roles in Alcoa, Arcelor Mittal Steel, and most recently, Cliffs Natural Resources, where he served as Executive Vice President, Chief Human Resources Officer from 2010 to 2014.	63

Jeffrey R. Needham	Mr. Needham was named Executive Vice President and President of Consumer Healthcare Americas in October 2009. He served as Senior Vice President of Commercial Business Development for Consumer Healthcare from March 2005 through October 2009. Previously, he served as Senior Vice President of International from November 2004 to March 2005. He served as Managing Director of Perrigo's U.K. operations from May 2002 to November 2004 and as Vice President of Marketing from 1993 to 2002.	62
Grainne Quinn	Dr. Quinn was named Executive Vice President in July 2016 and has served as Chief Medical Officer since November 2015. Prior to that she served as Vice President and Head of Global Patient Safety from January 2014 until November 2015. Dr. Quinn was Vice President and Head of Global Pharmacovigilance and Risk Management for Elan from April 2009 until December 2013 when the Company acquired Elan.	49
Ronald L. Winowiecki	Mr. Winowiecki was appointed Chief Financial Officer in February 2018. He served as Acting Chief Financial Officer from February 2017 to February 2018; Senior Vice President of Business Finance from January 2014 to February 2017; Vice President for Treasury and Accounting Shared Services from September 2011 to December 2013; and the Company's Corporate Vice President Treasurer from October 2008 to August 2011.	52

PART II.

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

Prior to June 6, 2013, our common equity traded on the Nasdaq Global Select Market under the symbol PRGO. Since June 6, 2013, our common equity has traded on the New York Stock Exchange 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 since March 16, 2005 under the same symbol. As of February 22, 2019, there were 1,470 record holders of our ordinary shares.

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, 2013 through December 31, 2018.

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

*$100 invested on December 31, 2013 in stock or index - including reinvestment of dividends. Indexes calculated on month-end basis.
** Perrigo Company prior to December 31, 2013. Perrigo Company plc beginning December 18, 2013.

In October 2015, the Board of Directors approved a three-year share repurchase plan of up to $2.0 billion. We did not repurchase any shares under the share repurchase plan during the three months ended December 31, 2018. During the year ended December 31, 2018, we repurchased 5.1 million ordinary shares at an average repurchase price of $77.93 per share, for a total of $400.0 million. During the year ended December 31, 2017, we repurchased 2.7 million ordinary shares at an average repurchase price of $71.72 per share, for a total of $191.5 million. Following the expiration of our 2015 Authorization, in October 2018, our Board of Directors authorized up to $1.0 billion of share repurchases with no expiration date, subject to the Board of Directors' approval of the pricing parameters and amount that may be repurchased under each specific share repurchase program.

ITEM 6. SELECTED FINANCIAL DATA

The Consolidated Statements of Operations data set forth below with respect to the years ended December 31, 2018, December 31, 2017, and December 31, 2016, and the Consolidated Balance Sheet data at December 31, 2018 and December 31, 2017 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 Statements of Operations data set forth below with respect to the the six months ended December 31, 2015 and December 27, 2014, and the year ended June 27, 2015 and the Consolidated Balance Sheet data at December 31, 2016, December 31, 2015, December 27, 2014 and June 27, 2015 are derived from audited consolidated financial statements not included in this report.

	Year Ended			Six Months Ended		Year Ended
(in millions, except per share amounts)	December 31, 2018	December 31, 2017	December 31, 2016[1]	December 31, 2015[2]	December 27, 2014[3]	June 27, 2015[4]
Statements of Operations Data						
Net sales	$4,731.7	$4,946.2	$5,280.6	$2,632.2	$1,844.7	$4,227.1
Cost of sales	2,900.2	2,966.7	3,228.8	1,553.3	1,170.9	2,582.9
Gross profit	1,831.5	1,979.5	2,051.8	1,078.9	673.8	1,644.2
Operating expenses	1,595.0	1,381.3	4,051.5	1,011.3	384.1	971.7
Operating income (loss)	$236.5	$598.2	$(1,999.7)	$67.6	$289.7	$672.5
Net income (loss)	$131.0	$119.6	$(4,012.8)	$42.5	$180.6	$136.1
Diluted earnings (loss) from continuing operations per share	$0.95	$0.84	$(28.01)	$0.29	$1.34	$0.97
Dividends declared per share	$0.76	$0.64	$0.58	$0.25	$0.21	$0.46

(1) Includes the results of operations for assets acquired from Barr Laboratories, Inc. and assets acquired from Matawan Pharmaceuticals, LLC for the five months and eleven months and one week ended December 31, 2016, respectively.

(2) Includes the results of operations of Naturwohl and the GSK, ScarAway®, and Entocort® asset acquisitions for the two and a half months, three months, three months, and two weeks ended December 31, 2015, respectively.

(3) Includes the results of operations for assets acquired from Lumara Health, Inc. for the two months ended December 27, 2014.

(4) Includes the results of operations for assets acquired from Lumara Health, Inc. and the results of operations of Omega Pharma Invest N.V. and Gelcaps Exportadora de Mexico, S.A. de C.V. for the eight, three, and two months ended June 27, 2015, respectively.

(in millions)	December 31, 2018	December 31, 2017	December 31, 2016	December 31, 2015	December 27, 2014	June 27, 2015
Balance Sheet Data						
Cash and cash equivalents	$ 551.1	$ 678.7	$622.3	$ 417.8	$ 3,596.1	$785.6
Total assets	$ 10,983.4	$ 11,628.8	$13,870.1	$ 19,349.6	$ 16,508.4	$19,591.9
Long-term debt, less current portion	$ 3,052.2	$ 3,270.8	$5,224.5	$ 4,971.6	$ 4,439.4	$5,246.9

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis ("MD&A") is intended to provide readers with an understanding of our financial condition, results of operations, and cash flows by focusing on changes in certain key measures from year to year. This MD&A is provided as a supplement to, and should be read in

conjunction with, our Consolidated Financial Statements and accompanying Notes found in Item 8 of this report. See also "Cautionary Note Regarding Forward-Looking Statements."

EXECUTIVE OVERVIEW

Perrigo Company plc was incorporated under the laws of Ireland on June 28, 2013 and became the successor registrant of Perrigo Company, a Michigan corporation, on December 18, 2013 in connection with the acquisition of Elan Corporation, plc ("Elan"). 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.

We are a leading global healthcare company that has been delivering value to our customers and consumers by providing Quality Affordable Healthcare Products®. Founded in 1887 as a packager of home remedies, we have built a unique business model that is best described as the convergence of a fast-moving consumer goods company, a high-quality pharmaceutical manufacturing organization and a world-class supply chain network. We are one of the world's largest manufacturers of over-the-counter (“OTC”) healthcare products and suppliers of infant formulas for the store brand market. We are also a leading provider of branded consumer health and wellness products throughout Europe and a leading producer of generic prescription pharmaceutical topical products such as creams, lotions, gels, and nasal sprays ("extended topicals"). We are headquartered in Ireland and sell our products primarily in North America and Europe, as well as in other markets, including Israel, Mexico, Australia, and Canada.

Our fiscal year begins on January 1 and ends on December 31 of each year. We end 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.

Our Segments

Our operating and reportable segments are as follows:

- **Consumer Healthcare Americas** (**"CHCA"**), comprises our U.S., Mexico and Canada consumer healthcare business (OTC, contract manufacturing, infant formula and animal health categories).
- **Consumer Healthcare International** (**"CHCI"**), comprises our branded consumer healthcare business primarily in Europe and our consumer focused businesses in the United Kingdom ("U.K."), Australia, and Israel. This segment also includes our U.K. liquid licensed products business.
- **Prescription Pharmaceuticals** (**"RX"**), comprises our U.S. Prescription Pharmaceuticals business.

Our segments reflect the way in which our management makes operating decisions, allocates resources and manages the growth and profitability of the Company.

For information on each segment, refer to Item 1. Business - Our Segments. For results by segment and geographic locations see below "Segment Results" and Item 8. Note 2 and 19. See Item 1. Business for information on our business environment and competitive landscape.

Strategy

Our strategy has been to deliver Quality Affordable Healthcare Products® by leveraging our global infrastructure to expand our product offerings, thereby providing new innovative products and product line extensions to existing consumers and servicing new healthcare consumers through entry into adjacent or new markets. We accomplish this strategy by investing in and continually improving all aspects of our five

strategic pillars:

- High quality;
- Superior customer service;
- Leading innovation;
- Best cost; and
- Empowered people.

We utilize shared services and Research and Development ("R&D") centers of excellence in order to help ensure consistency in our processes around the world, and to maintain focus on our five strategic pillars.

We have grown rapidly in recent years through a combination of organic and inorganic growth. We continually reinvest in our R&D pipeline and work with partners as necessary to strive to be first-to-market with new products. Our organic growth has been and will continue to be driven by successful new product launches in all our segments. Over time, we expect to continue to grow inorganically through expansion into adjacent products, product categories, and channels, as well as potentially through entry into new geographic markets. We evaluate potential acquisition targets using a return on invested capital metric.

Vision Transformation

Upon the arrival of our new CEO and President Murray Kessler, he and his leadership team made their first priority to set a new vision for the Company that will help us transform into a consumer-focused company. That vision is "To make lives better by bringing "*Quality, Affordable Self-Care Products™"* that consumers trust everywhere they are sold." The new vision for the future is designed to support the shifting focus on our consumer branded and store brand portfolio and our global reach and the opportunities for growth we see ahead of us, while remaining loyal to our heritage. The vision represents an evolution from healthcare to self-care, which takes advantage of a massive global trend and opens up a large number of adjacent growth opportunities for the Company.

Competitive Advantage

Our consumer-facing business model combines the unique competencies of a fast-moving consumer goods company and a pharmaceutical manufacturing company with the supply chain breadth necessary to support customers in the markets we serve. These durable business model competencies align with our five strategic pillars and provide us a competitive advantage in the marketplace. We fully integrate quality in our operational systems across all products. Our ability to manage our supply chain complexity across multiple dosage forms, formulations, and stock-keeping units, as well as acquisitions, integration, and hundreds of global partners provides value to our customers. Product development capacity and life cycle management are at the core of our operational investments. Globally we have 20 manufacturing plants that are all in good regulatory compliance standing and have systems and structures in place to guide our continued success. Our leadership team is fully engaged in aligning all our metrics and objectives around sustainable compliance with industry associations and regulatory agencies.

Among other things, we believe the following give us a competitive advantage and provide value to our customers:

- Leadership in first-to-market product development and product life cycle management;
- Turn-key regulatory and promotional capabilities;
- Management of supply chain complexity and utilizing economies of scale;
- Quality and cost effectiveness throughout the supply chain creating a sustainable, low-cost network; and
- Expansive pan-European commercial infrastructure, brand-building capabilities, and a diverse product portfolio.

Highlights

Year Ended December 31, 2018

- On August 9, 2018, we announced a plan to separate our RX business, which, when completed, will enable us to focus on expanding our consumer-facing businesses. We have begun the preparations for the separation, which may include a possible sale, spin-off, merger or other form of separation. While we are currently targeting to complete the separation by the end of 2019, the form of separation may delay its completion beyond this date. In connection with the proposed separation, we anticipate incurring significant preparation costs, excluding restructuring expenses and transaction costs, in the range of $45.0 million to $80.0 million depending on the final structure of a transaction, with a spin-off resulting in costs at the higher end of this range.

- During the year ended December 31, 2018, Tysabri® met the 2018 global net sales threshold resulting in a $170.1 million gain. We received the $250.0 million royalty payment on February 22, 2019.

- During the year ended December 31, 2018, we repurchased $400.0 million worth of shares as part of our authorized share repurchase plan.

Year Ended December 31, 2017

- On March 27, 2017, we completed the sale of our Tysabri® financial asset to Royalty Pharma for up to $2.85 billion, consisting of $2.2 billion in cash and up to $250.0 million and $400.0 million in milestone payments if the royalties on global net sales of Tysabri® that are received by Royalty Pharma meet specific thresholds in 2018 and 2020, respectively. As a result of this transaction, we derecognized the Tysabri® financial asset and recorded a $17.1 million gain.

- On April 6, 2017, we completed the sale of our India Active Pharmaceutical Ingredient ("API") business to Strides Shasun Limited for $22.2 million, inclusive of an estimated working capital adjustment. The sale did not have a material impact on our operations.

- On August 25, 2017, we completed the sale of our Russian business to Alvogen Pharma LLC for €12.7 million ($15.1 million), inclusive of an estimated working capital adjustment. The sale did not have a material impact on our operations.

- On November 21, 2017, we completed the sale of our Israel API business to SK Capital, for a sale price of $110.0 million, which resulted in an immaterial gain.

- We completed $2.6 billion of debt repayments.

- We repurchased $191.5 million worth of shares as part of our authorized share repurchase plan.

- We executed initiatives related to our cost optimization strategy that was announced on February 21, 2017. Restructuring charges totaled $61.0 million.

Year Ended December 31, 2016

- Consistent with previously announced actions, we added a number of positions and processes to our Dublin headquarters across a range of corporate functions, including supply chain/global operations, procurement, enterprise risk management, and corporate finance, leveraging the strength of our global platform.

- On September 29, 2016, we repaid $500.0 million outstanding under our 1.300% Senior Notes due 2016.

- On August 5, 2016, we completed the sale of our U.S. Vitamins, Minerals, and Supplements ("VMS") business to International Vitamins Corporation for $61.8 million inclusive of an estimated working capital adjustment.

RESULTS OF OPERATIONS

CONSOLIDATED

Recent Developments

Irish Tax Appeals Commission Notice of Amended Assessment

Perrigo Pharma International, a designated activity company organized under the laws of Ireland, formerly known as Elan Pharma International Limited (“Elan Pharma”) and currently a subsidiary of Perrigo Company plc, timely filed an appeal on December 27, 2018 with the Irish Tax Appeals Commission regarding a Notice of Amended Assessment (“NoA”) issued by the Irish Office of the Revenue Commissioners (“Irish Revenue”) for the calendar year

ended December 31, 2013. The NoA is dated November 29, 2018, and assesses an Irish corporation tax liability against Elan Pharma in the amount of €1,636 million, not including interest or any applicable penalties.

Perrigo acquired Elan Pharma through the December 2013 business combination between Perrigo's predecessor and Elan Corporation, plc. The NoA relates to the tax treatment of the April 2013 sale by Elan Pharma of Tysabri® intellectual property and related assets to Biogen Idec. As previously reported, the consideration paid by Biogen Idec took the form of an upfront payment and future contingent payments. The upfront payment received from Biogen Idec in 2013 and contingent payments received in subsequent years were recognized as trading income in Elan Pharma's tax returns filed with Irish Revenue. This treatment is consistent with Elan Pharma's activities for two
decades relating to the active management of intellectual property rights, which includes acquiring, developing, holding, exploiting, dealing in and disposing of intellectual property rights for use in the pharmaceutical industry.

On October 30, 2018, Irish Revenue issued an audit findings letter to Elan Pharma asserting the claim that (a) IP sales transactions by Elan Pharma, including the sale of Tysabri®, were not part of the trade of Elan Pharma and therefore should have been treated as chargeable gains subject to an effective 33% tax rate, rather than the 12.5% tax rate applicable to trading income, and (b) all amounts received in respect of both the Tysabri® transaction and the related transaction entered into with RPI Finance Trust in 2017 should be taxed in Elan Pharma's 2013 tax year.

We disagree with both the basis on which Elan Pharma has been assessed and the methodology used to calculate the amount set out in the NoA. We believe the NoA is without merit and that Irish Revenue's position is incorrect as a matter of law. Accordingly, we filed an appeal of the NoA on December 27, 2018 and will pursue all available administrative and judicial avenues as may be necessary or appropriate. As part of this strategy to pursue all available administrative and judicial avenues, Elan Pharma was, on February 25, 2019, granted leave by the Irish High Court to seek judicial review of the issuance of the NoA. The judicial review filing is based on our belief that Elan Pharma's legitimate expectations as a taxpayer have been breached, not on the merits of the NoA itself. If we are ultimately successful in the judicial review proceedings, the NoA will be invalidated and Irish Revenue will not be able to re-issue the NoA. The proceedings before the Tax Appeals Commission has been stayed until a decision on the judicial review application has been made, which could take up to, or more than, a year. No payment of any amount related to this assessment is required to be made, if at all, until all applicable proceedings have been completed, which could take a number of years. However, while we believe our position to be correct, there can be no assurance of an ultimate favorable outcome, and if the matter is ultimately resolved unfavorably it would have a material adverse impact on us, including on liquidity and capital resources (refer to Item 1A. Risk Factors - Tax related Risks and Item 8. Note 14).

Impairments

Throughout the years ended December 31, 2018, December 31, 2017, and December 31, 2016, we identified impairment indicators for various assets across our different segments, and therefore, we performed impairment testing. Below is a summary of the impairment charges by segment (in millions):

	Year Ended December 31, 2018		
	CHCA[1]	CHCI	Total

Goodwill	$136.7	$—	$136.7
Indefinite-lived intangible assets	27.7	—	27.7
Definite-lived intangible assets	48.9	0.7	49.6
Assets held-for-sale	0.6	1.1	1.7
IPR&D	8.7	—	8.7
	$222.6	$1.8	$224.4

(1) Relates primarily to animal health and certain IPR&D.

Perrigo Company plc - Item 7
Consolidated

	Year Ended December 31, 2017				
	CHCA[1]	CHCI[2]	RX[3]	Other[4]	Total
Definite-lived intangible assets	$—	$ —	$19.7	$ —	$19.7
Assets held-for-sale	—	3.7	—	3.3	7.0
IPR&D	—	1.1	11.6	—	12.7
Property, plant, and equipment	4.5	—	3.6	—	8.1
	$4.5	$ 4.8	$34.9	$ 3.3	$47.5

(1) Relates to certain idle property, plant and equipment.
(2) Relates primarily to our Russian business, which was sold August 25, 2017.
(3) Relates primarily to intangible assets acquired through the Lumara Health, Inc. acquisition and IPR&D assets acquired in conjunction with certain Development-Stage Rx Products.
(4) Relates to our Israel API business, which was sold November 21, 2017.

	Year Ended December 31, 2016				
	CHCA[1]	CHCI[2]	RX[3]	Other[4]	Total
Goodwill	$24.5	$868.4	$—	$199.6	$1,092.5
Indefinite-lived intangible Assets	0.4	849.1	—	—	849.5
Definite-lived intangible assets	—	321.4	342.2	2.0	665.6
Assets held-for-sale	9.9	—	—	6.3	16.2
IPR&D	—	3.5	—	—	3.5
Property, plant, and equipment	3.5	—	0.2	—	3.7
	$38.3	$2,042.4	$342.4	$207.9	$2,631.0

(1) Relates primarily to goodwill acquired through the Sergeant's Pet Care Products, Inc. and Velcera Inc. acquisitions.
(2) Relates primarily to goodwill and certain intangible assets acquired in conjunction with the Omega acquisition.
(3) Relates primarily to our intangible assets acquired in conjunction with the Entocort® acquisition.
(4) Relates primarily to goodwill from our Elan acquisition that was in our former Specialty Sciences segment.

Perrigo Company plc - Item 7
Consolidated

Consolidated Results

(in millions)	Year Ended December 31, 2018		December 31, 2017		December 31, 2016	
Net sales	$4,731.7		$ 4,946.2		$ 5,280.6	
Gross profit	$1,831.5		$ 1,979.5		$ 2,051.8	
Gross profit %	38.7	%	40.0	%	38.9	%
Operating expenses	$1,595.0		$ 1,381.3		$ 4,051.5	
Operating expenses %	33.7	%	27.9	%	76.7	%
Operating income (loss)	$236.5		$ 598.2		$ (1,999.7	)
Operating income (loss) %	5.0	%	12.1	%	(37.9	)%

*Total net sales by geography is derived from the location of the entity that sells to a third party.

CONSUMER HEALTHCARE AMERICAS

Recent Developments

- On May 29, 2018, we entered into a license agreement with Merck Sharp & Dohme Corp. ("Merck") that will allow us to develop and commercialize an OTC version of Nasonex-branded products, as well as other products containing the same active ingredient. In connection with this license agreement, we paid an upfront license fee of $50.0 million. In addition, if we achieve certain development milestones, we will make future milestone and royalty payments.

- During the year ended December 31, 2018, we identified indications of impairment in the animal health reporting unit. The impairment indicators related to changes in channel dynamics, a strategic decision to re-prioritize our brands, and a decline in the forecasted outlook of the reporting unit. We recorded goodwill and intangible asset impairment charges of $213.3 million in Impairment charges on the Consolidated Statements of Operations.

Perrigo Company plc - Item 7
CHCA

Segment Results

Year Ended December 31, 2018 vs. December 31, 2017

(in millions)	Year Ended December 31, 2018		December 31, 2017	
Net sales	$2,411.6		$ 2,429.9	
Gross profit	$762.2		$ 817.8	
Gross profit %	31.6	%	33.7	%
Operating income	$147.6		$ 445.0	
Operating income %	6.1	%	18.3	%

Net sales decreased $18.3 million, or 1%, due primarily to:

- The absence of $32.1 million in sales of discontinued products; and
- A net decrease of $31.5 million in sales of existing products due to:
  - Lower sales in our animal health category due to lost distribution and channel dynamics;
  - Ongoing pricing pressure, which we expect to continue for the foreseeable future, and lower sales volumes in our gastrointestinal category; partially offset by
  - Higher sales volumes in our analgesics and dermatologic categories; and
  - Unfavorable foreign currency translation of $3.4 million; partially offset by
- New product sales of $48.7 million due primarily to the launches of esomeprazole magnesium (store brand equivalent to Nexium® 24HR capsules), omeprazole delayed release orally disintegrating tablets, and infant formula products.

Operating income decreased $297.4 million, or 67%, due primarily to:

- A decrease of $55.6 million in gross profit, or a 210 basis point decrease in gross profit as a percentage of net sales, due primarily to operating variances and increased input costs, lower sales in the higher margin animal health business and pricing pressure.

- An increase of $241.8 million in operating expenses due primarily to:
  - Impairment charges due primarily to animal health goodwill and intangible assets of $222.6 million; and
  - Increased R&D expense of $44.8 million due primarily to a $50.0 million upfront license fee payment to enter into a license agreement with Merck; partially offset by
  - Decreased Restructuring expense of $26.9 million related to the cost reduction initiatives taken in the prior year.

Year Ended December 31, 2017 vs. December 31, 2016

(in millions)	Year Ended December 31, 2017		December 31, 2016	
Net sales	$2,429.9		$2,507.1	
Gross profit	$817.8		$825.2	
Gross profit %	33.7	%	32.9	%

Operating income	$445.0		$399.8	
Operating income %	18.3	%	15.9	%

Net sales decreased $77.2 million, or 3%, due to:

- The absence of $110.2 million in sales attributable to the U.S. VMS business;
- A net decrease of $21.5 million in sales of existing products due to pricing pressures and lower volumes in certain categories; and
- The absence of $14.0 million in sales of discontinued products; partially offset by
- New product sales of $68.7 million related primarily to the launches of fluticasone nasal spray (store brand equivalent to Flonase®), smoking cessation products and esomeprazole magnesium (store brand equivalent to Nexium® 24HR capsules).

Operating income increased $45.2 million, or 11%, due primarily to:

- A decrease of $7.4 million in gross profit due to:
  - The absence of $17.6 million in gross profit as a result of the sale of the U.S. VMS business; and
  - Pricing pressures in certain categories; partially offset by
  - Favorable product mix in certain categories; and
  - Positive contributions from supply chain efficiencies.

- A decrease of $52.6 million in operating expenses due to:
  - The absence of $36.7 million in goodwill and intangible asset impairment charges related to the sale of the U.S. VMS business, previously held-for-sale assets associated with our animal health pet treats plant and our animal health business;
  - Decreased selling and administrative expenses of $31.0 million due primarily to timing of promotions related to our animal health category and savings related to our cost reduction initiatives taken in the prior year;
  - Decreased R&D expenses of $8.2 million due to timing of clinical trials, reduced spending on infant formula clinical trials and lower costs related to our cost reduction initiatives; and
  - A $4.1 million gain related to contingent consideration; offset partially by
  - Increased restructuring expenses of $21.8 million related primarily to strategic organizational enhancements; and
  - A $4.5 million impairment charge recorded on idle property, plant and equipment.

- An increase of 80 basis points in gross profit as a percentage of net sales due primarily to favorable product mix and supply chain efficiencies.

CONSUMER HEALTHCARE INTERNATIONAL

Recent Developments

- Management continues to implement its previously disclosed strategy for brand prioritization, sales force restructuring, and manufacturing insourcing, which is expected to reduce selling costs, improve operating margins and focus on higher value OTC products. As part of this strategy, we implemented a new restructuring plan in our CHCI segment that is expected to improve our cost structure.

Perrigo Company plc - Item 7
CHCI

Segment Results

Year Ended December 31, 2018 vs. December 31, 2017

(in millions)	Year Ended December 31, 2018		December 31, 2017	
Net sales	$1,495.9		$ 1,491.0	
Gross profit	$702.5		$ 682.0	
Gross profit %	47.0	%	45.7	%
Operating income	$16.5		$ 12.5	
Operating income %	1.1	%	0.8	%

Net sales increased $4.9 million due primarily to:

- New product sales of $77.8 million; and
- Favorable foreign currency translation of $36.9 million; partially offset by
- A net decrease of $57.3 million in sales of existing products due primarily to lower sales in the lifestyle and cough/cold/allergy/sinus categories;
- The absence of $33.0 million in sales attributable to the exited Russian business and prior year distribution phase out initiatives; and
- The absence of $19.7 million in sales of discontinued products.

Operating income increased $4.0 million, or 33%, due primarily to:

- An increase of $20.5 million in gross profit, or a 130 basis point increase in gross profit as a percentage of net sales, due primarily to brand prioritization and exit of low margin businesses, improved pricing and benefits from continued insourcing initiatives.

- An increase of $16.5 million in operating expenses due primarily to:
- Increased selling and administration expenses of $11.1 million due primarily to the effect of unfavorable foreign currency translation; and
- Increased R&D expense of $3.2 million due primarily to innovation investments and the effect of unfavorable foreign currency translation.

Year Ended December 31, 2017 vs. December 31, 2016

(in millions)	Year Ended December 31, 2017		December 31, 2016	
Net sales	$1,491.0		$1,652.2	
Gross profit	$682.0		$693.4	
Gross profit %	45.7	%	42.0	%
Operating income (loss)	$12.5		$(2,087.4)	
Operating income (loss) %	0.8	%	(126.3	)%

Net sales decreased $161.2 million, or 10%, due to:

- The absence of $200.3 million in sales attributable to the cancellation of unprofitable distribution contracts;
- The absence of $14.7 million in sales of discontinued products; and
- A net decrease of $11.3 million in sales of existing products due primarily to the absence of sales from our exited Russian business; partially offset by
- New product sales of $64.1 million.

Perrigo Company plc - Item 7
CHCI

Operating income increased $2.1 billion due primarily to:

- A decrease of $11.4 million in gross profit due primarily to:
  - Lower sales volumes; and
  - Lower margins in our U.K. store brand business; partially offset by
  - Operational efficiencies across the organization.

- A decrease of $2.1 billion in operating expenses due primarily to:
  - The absence of $2.0 billion in goodwill and intangible asset impairment charges recorded in the prior year; and
  - A decrease in selling and administrative expenses of $66.6 million due to previously announced strategic initiatives to better align promotional investments with sales and cost reduction initiatives taken in the current year; offset partially by
  - A $4.8 million impairment charge recorded related to the Russian business; and
  - Increased restructuring expense of $3.8 million related to strategic organizational enhancements.

- An increase of 370 basis points in gross profit as a percentage of net sales due primarily to improved product mix primarily driven by the cancellation of certain unprofitable distribution contracts.

PRESCRIPTION PHARMACEUTICALS

Recent Trends and Developments

- We continue to experience a significant year-over-year reduction in pricing in our RX segment due to competitive pressures. This softness in pricing is attributable to various factors, including increased focus from customers to capture competition in specific products, supply chain productivity savings, and consolidation of certain customers. While in the fourth quarter of 2018, we experienced a year-over-year decrease in pricing pressure, we expect softness in pricing to continue to impact the segment for the foreseeable future.

- On August 24, 2018, we purchased the Abbreviated New Drug Application ("ANDA") for Diclofenac Sodium Gel, 3% ("Diclo 3%") for $30.4 million in cash, which we capitalized as a developed product technology intangible asset. Diclo 3% was launched at the end of December 2018.

Segment Results

Year Ended December 31, 2018 vs. December 31, 2017

(in millions)	Year Ended December 31, 2018		December 31, 2017	
Net sales	$824.2		$ 969.7	
Gross profit	$366.9		$ 449.7	
Gross profit %	44.5	%	46.4	%
Operating income	$222.6		$ 307.6	
Operating income %	27.0	%	31.7	%

Net sales decreased $145.5 million, or 15%, due to:

- A net decrease of $174.1 million in sales of existing products due primarily to increased competition driving pricing pressure and decreased sales volumes of certain products; and
- The absence of $14.6 million in sales of discontinued products; partially offset by
- New product sales of $43.2 million due primarily to Testosterone Gel 1.62% (generic equivalent to Androgel®).

Perrigo Company plc - Item 7
RX

Operating income decreased $85.0 million, or 28%, due primarily to:

- A decrease of $82.8 million in gross profit, or a 190 basis point decrease in gross profit as a percentage of net sales, due primarily to pricing pressure and unfavorable product mix.

- An increase of $2.2 million in operating expense due primarily to:
  - The absence of a gain of $23.0 million for the sale of certain ANDAs recognized in the prior year; and;
  - The absence of a gain of $15.0 million related to contingent consideration adjustments; partially offset by
  - The absence of impairments of $34.9 million related to certain definite-lived intangible assets and In-Process Research and Development ("IPR&D").

Year Ended December 31, 2017 vs. December 31, 2016

(in millions)	Year Ended December 31, 2017		Year Ended December 31, 2016	
Net sales	$969.7		$1,042.8	
Gross profit	$449.7		$501.1	
Gross profit %	46.4	%	48.1	%
Operating income (loss)	$307.6		$(0.2)	
Operating income %	31.7	%	—	%

Net sales decreased $73.1 million, or 7%, due to:

- A net decrease of $78.5 million in sales of existing products due primarily to pricing pressures across the portfolio;
  - Lower Entocort® net sales of $67.2 million; and
  - The absence of $3.3 million in sales of discontinued products; partially offset by
  - New product sales of $75.9 million due primarily to sales of Scopolamine and Testosterone 2% topical (generic equivalent to Axiron®).

Operating income increased $307.8 million due primarily to:

- A decrease of $51.4 million in gross profit, or a 170 basis point decrease in gross profit as a percentage of net sales, due primarily to:
  - Lower Entocort® net sales; and
  - Pricing pressure.

- A decrease of $359.2 million in operating expenses due to:
  - The absence of a $342.2 million impairment charge related to the Entocort® intangible asset;
  - A $23.0 million gain on sales of certain ANDAs;
  - A $15.4 million net gain related to contingent consideration;
  - Decreased Selling expenses of $17.4 million due primarily to the prior year specialty pharmaceuticals sales force restructuring initiative; and

- Decreased R&D expenses of $8.3 million due to timing of clinical trials, lower legal spend, and lower ongoing costs on certain projects; offset partially by
- Impairment charges related to certain definite-lived intangible assets, certain fixed assets and IPR&D of $34.9 million;
- Increased Administration expenses of $6.2 million due primarily to the settlement of our antitrust violation lawsuit; and
- Increased restructuring expenses of $3.8 million related to strategic organizational enhancements.

Perrigo Company plc - Item 7
Other

OTHER

We previously had two legacy segments, Specialty Sciences and Other, which contained our Tysabri® financial asset and API businesses, respectively, which we divested. Following these divestitures, there were no substantial assets or operations left in either of these segments. Effective January 1, 2017, all expenses associated with our former Specialty Sciences segment were moved to unallocated expenses.

During the year ended December 31, 2017, we completed the divestment of the Tysabri® financial asset to Royalty Pharma for up to $2.85 billion, consisting of $2.2 billion in cash and up to $250.0 million and $400.0 million in milestone payments if the royalties on global net sales of Tysabri® that are received by Royalty Pharma meet specific thresholds in 2018 and 2020, respectively. As a result of this transaction, we transferred the entire financial asset to Royalty Pharma and recorded a $17.1 million gain in Change in financial assets.

During the year ended December 31, 2017, we completed the sale of our India API business to Strides Shasun Limited. We received $22.2 million in proceeds, resulting in an immaterial gain recorded in Other (income) expense, net on the Consolidated Statements of Operations. Prior to closing the sale, we determined that the carrying value of the India API business exceeded its fair value less the cost to sell, resulting in an impairment charge of $35.3 million, which was recorded in Impairment charges on the Consolidated Statements of Operations for the year ended December 31, 2016.

During the year ended December 31, 2017, we completed the sale of our Israel API business to SK Capital for a sale price of $110.0 million, which resulted in an immaterial gain recorded in Other (income) expense, net on the Consolidated Statements of Operations.

Unallocated Expenses

Unallocated expenses are comprised of certain corporate services not allocated to our reporting segments and are recorded above Operating income on the Consolidated Statements of Operations. Unallocated expenses were as follows (in millions):

Year Ended December 31, 2018	December 31, 2017	December 31, 2016
$150.1	$ 174.7	$ 116.6

The $24.6 million decrease for the year ended December 31, 2018 compared to the prior year was due primarily to an insurance recovery of $17.8 million, a decrease in legal and consulting fees of $8.7 million and, a decrease in Restructuring expense of $5.5 million related to strategic organizational enhancements; partially offset by an increase in employee-related expenses of $5.2 million.

The $58.1 million increase for the year ended December 31, 2017 compared to the prior year was due primarily to an increase in share-based compensation expense of $12.6 million driven primarily by the resignation of certain executives, an increase of $41.1 million of administrative expenses driven by legal fees, consulting fees and employee-related expenses, and an increase in Restructuring expenses of $6.0 million related to strategic organizational enhancements.

Interest, Other (Income) Expense and Change in Financial Assets (Consolidated)

(in millions)	Year Ended December 31, 2018	December 31, 2017	December 31, 2016
Change in financial assets	$(188.7)	$ 24.9	$ 2,608.2
Interest expense, net	$128.0	$ 168.1	$ 216.6
Other (income) expense, net	$6.1	$ (10.1)	$ 22.7
Loss on extinguishment of debt	$0.5	$ 135.2	$ 1.1

Change in Financial Assets

During the year ended December 31, 2018, Tysabri® met the 2018 global net sales threshold resulting in an increase to the asset and a gain of $170.1 million recognized in Change in financial assets on the Consolidated Statement of Operations. Due to higher projected global net sales of Tysabri® and the estimated probability of achieving the 2020 contingent milestone payment, the fair value of the 2020 Royalty Pharma contingent milestone payment increased $18.6 million during the year ended December 31, 2018.

During the year ended December 31, 2017, we announced the completed divestment of our Tysabri® financial asset to Royalty Pharma, resulting in a $17.1 million gain. As a result of a decrease in the estimated Tysabri® revenue due to a competitor's pipeline product, Ocrevus®, the fair value of the Royalty Pharma contingent milestone payments decreased $42.0 million.

During the year ended December 31, 2016 Ocrevus® entered the market, leading us to evaluate strategic alternatives for the Tysabri® financial asset and reduce the fair value of the Tysabri® financial asset by $2.6 billion.

Interest Expense, Net

The $40.1 million decrease during the year ended December 31, 2018 compared to the prior year was the result of early debt repayments made during the year ended December 31, 2017.

The $48.5 million decrease during the year ended December 31, 2017 compared to the prior year was the result of early debt repayments made during the year ended December 31, 2017.

Other (Income) Expense, Net

The $16.2 million decrease during the year ended December 31, 2018 compared to the prior year was due primarily to the absence of $10.0 million in milestone income related to royalty rights, a $9.5 million loss on our fair value investment securities, and $4.5 million of unfavorable changes in revaluation of monetary assets and liabilities held in foreign currencies; partially offset by the absence of a $5.9 million loss on hedges related to the extinguishment of debt in the prior year, and a $2.7 million gain on our equity method investments.

The $32.8 million decrease during the year ended December 31, 2017 compared to the prior year was due primarily to the absence of a $22.3 million equity investment impairment, $8.2 million of favorable changes in revaluation of monetary assets and liabilities held in foreign currencies and a $3.2 million reduction in equity method losses.

Loss on Extinguishment of Debt

During the year ended December 31, 2017, we recorded a $135.2 million loss on extinguishment of debt, which consisted of tender premium on debt repayments, transaction costs, write-off of deferred financing fees, and bond discounts.

Income Taxes (Consolidated)

The effective tax rates were as follows:

Year Ended December 31, 2018	December 31, 2017	December 31, 2016
54.9%	57.3 %	17.2 %

The effective tax rate for the year ended December 31, 2018 decreased in comparison to the prior year due primarily to the 2017 sale of API Israel and the one-time U.S. transition toll tax, offset by additional tax expense due to valuation allowances in Belgium and state tax recorded for the future distributions of foreign earnings recorded in 2018. The effective tax rate for the year ended December 31, 2017 was higher compared to the year ended

December 31, 2016 due to an increase in the valuation allowance position due to current year activity, tax law changes in the U.S. and increases in unrecognized tax benefits, offset by tax law changes in Belgium.

For the year ended December 31, 2017, statutory income tax rate changes in the U.S. and Belgium impacted the effective tax rate with a reduction to U.S. income tax expense of $2.4 million and increased Belgium income tax expense by $24.1 million. For the year ended December 31, 2016, statutory income tax rate changes, primarily in Europe, favorably impacted the effective tax rate by $27.9 million (refer to Item 8. Note 14).

FINANCIAL CONDITION, LIQUIDITY, AND CAPITAL RESOURCES

We finance our operations with internally generated funds, supplemented by credit arrangements with third parties and capital market financing. We routinely monitor current and expected operational requirements and financial market conditions to evaluate other available financing sources including revolving bank credit and securities offerings. In determining our future capital requirements we regularly consider, among other factors, known trends and uncertainties, such as the NoA and other contingencies. In that connection, we note that no payment of the additional amounts assessed by Irish Revenue pursuant to the NoA is currently required, and no such payment is expected to be required, unless and until a final determination of the matter is reached that is adverse to us. Based on the foregoing, management believes that our operations and borrowing resources are sufficient to provide for our short-term and long-term capital requirements, as described below. However, we continue to evaluate the impact of the above factors on liquidity and may determine that modifications to our capital structure are appropriate if market conditions deteriorate, if favorable capital market opportunities become available, or if any change in conditions relating to the NoA or other contingencies has a material impact on our capital requirements.

Cash and Cash Equivalents

* Working capital represents current assets less current liabilities, excluding cash and cash equivalents, and current indebtedness.

Cash, cash equivalents, cash flows from operations, and borrowings available under our credit facilities are expected to be sufficient to finance our liquidity and capital expenditures in both the short and long term. Although our lenders have made commitments to make funds available to us in a timely fashion under our revolving credit agreements and overdraft facilities, if economic conditions worsen or new information becomes publicly available impacting the institutions' credit rating or capital ratios, these lenders may be unable or unwilling to lend money pursuant to our existing credit facilities. Should our outlook on liquidity requirements change substantially from current projections, we may seek additional sources of liquidity in the future.

Cash Generated by (Used in) Operating Activities
Year Ended December 31, 2018 vs. December 31, 2017

The $105.9 million decrease in operating cash flow was due primarily to:

- Decreased net earnings after adjustments for items such as deferred income taxes, impairment charges, restructuring charges, changes in our financial assets, loss on extinguishment of debt, and depreciation and amortization;

- Changes in inventory due primarily to increased volumes and actions to improve customer service in our CHCA segment and increased volumes due to new product launches and changing market dynamics in our RX segment;

- Changes in accounts payable due primarily to timing of payments, mix of payment terms, and the absence of transactions related to the exited Russian business and prior year distribution phase out initiatives;

- Changes in accrued income taxes due primarily to U.S. Federal tax obligation payments made in the prior year, offset by expected tax refunds;

- Changes in accrued liabilities due primarily to the change in royalty and profit sharing accruals; and

- Changes in accounts receivable due primarily to the discontinuation of our Belgium accounts receivable factoring program, more than offset by timing of sales and receipt of payments in our CHCA and RX segments.

Year Ended December 31, 2017 vs. December 31, 2016

The $44.0 million increase in operating cash flow was due primarily to:

- Increased net earnings after adjustments for items such as deferred income taxes, impairment charges, restructuring charges, changes in our financial assets, loss on extinguishment of debt, and depreciation and amortization;

- Changes in accrued customer programs due primarily to new product launches, resulting in higher customer-related accruals, pricing dynamics in the RX segment, as well as timing of rebate and chargeback payments;

- Changes in accounts payable due primarily to changes to the Omega accounts payable structure that occurred in 2016;

- Changes in accrued liabilities due primarily to deferred revenue associated with BCH-Belgium distribution contracts and the absence of accruals related to the sale of our U.S. VMS business; partially offset by increased litigation accruals, and fair market value adjustments related to contingent consideration;

- Changes in inventory due to the build up of inventory levels to support customer demands in 2017; offset by improved inventory management in 2016; and

- Changes in accrued income taxes due primarily to Federal tax obligation payments made in the current year, offset by expected tax refunds.

Cash Generated by (Used in) Investing Activities
Year Ended December 31, 2018 vs. December 31, 2017

The $2.5 billion decrease in investing cash flow was due primarily to:

- Absence of the prior year completed divestment of our Tysabri® financial asset to Royalty Pharma, for which we received $2.2 billion in cash;
- Absence of prior year net proceeds from sale of business and other assets of $149.4 million;
- Decreased proceeds from royalty rights of $73.6 million; and
- Asset acquisitions of $35.6 million related primarily to Diclo 3%.

Cash used for capital expenditures totaled $102.6 million during the year ended December 31, 2018 compared to $88.6 million in the prior year. The increase in cash used for capital expenditures was due primarily to the increase in the number of manufacturing projects in the current year compared to the prior year. Capital expenditures for the next twelve months are anticipated to be between $145.0 million and $209.0 million related to manufacturing productivity, increased tablet and infant formula capacity and quality/regulatory projects. We expect to fund these estimated capital expenditures with funds from operating cash flows.

Year Ended December 31, 2017 vs. December 31, 2016

The $2.5 billion increase in investing cash flow was due primarily to:

- Completed divestment of our Tysabri® financial asset to Royalty Pharma, for which we received $2.2 billion in cash;
- Absence of the prior year acquisition of a portfolio of generic dosage forms and strengths of Retin-A®, a topical prescription acne treatment from Mattawan Pharmaceuticals, LLC for $416.4 million; and
- Absence of the prior year acquisition of Generic Benzaclin™ product rights for $62.0 million; partially offset by
- A decrease in proceeds from royalty rights of $266.4 million.

Cash used for capital expenditures totaled $88.6 million during the year ended December 31, 2017 compared to $106.2 million in the prior year. The decrease in cash used for capital expenditures was due primarily to the decrease in the number of manufacturing projects in the current year compared to the prior year.

Cash Generated by (Used in) Financing Activities

Year Ended December 31, 2018 vs. December 31, 2017

The $2.4 billion increase in financing cash flow was due primarily to:

- Decrease in payments on long-term debt and premium on early debt retirement of $2.1 billion and $116.1 million, respectively, due to debt extinguishment in 2017; and
- Issuance of $431.0 million of long-term debt in the current year; partially offset by
- An increase in share repurchases of $208.5 million.

Year Ended December 31, 2017 vs. December 31, 2016

The $2.7 billion decrease in financing cash flow was due primarily to:

- Increase in payments on long-term debt and premium on early debt retirement of $2.1 billion and $115.5 million, respectively, due to debt extinguishment in 2017;
- Absence of issuance of long-term debt of $1.2 billion in 2016; and
- Share repurchases of $191.5 million in 2017; partially offset by
- A decrease in borrowings (repayments) of revolving credit agreements and other financing, net of $809.3 million.

Share Repurchases

In October 2018, our Board of Directors authorized up to $1.0 billion of share repurchases with no expiration date, subject to the Board of Directors' approval of the pricing parameters and amount that may be repurchased under each specific share repurchase program.

Dividends

In January 2003, the Board of Directors adopted a policy of paying quarterly dividends. We paid dividends as follows:

	Year Ended December 31, 2018	December 31, 2017	December 31, 2016
Dividends paid (in millions)	$104.9	$ 91.1	$ 83.2
Dividends paid per share	$0.76	$ 0.64	$ 0.58

The declaration and payment of dividends, if any, is subject to the discretion of our Board of Directors and will depend on our earnings, financial condition, availability of distributable reserves, capital and surplus requirements, and other factors our Board of Directors may consider relevant.

Borrowings and Capital Resources

Overdraft Facilities

We have overdraft facilities available that we use to support our cash management operations. We report any balances outstanding in "Other Financing" in Item 8, Note 10. There were no borrowings outstanding under these facilities at December 31, 2018. The balance outstanding under the overdraft facilities was $6.9 million at December 31, 2017.

Accounts Receivable Factoring

We have accounts receivable factoring arrangements with non-related third-party financial institutions (the “Factors”). Pursuant to the terms of the arrangements, we sell to the Factors certain of our accounts receivable balances on a non-recourse basis for credit approved accounts. An administrative fee per invoice is charged on the gross amount of accounts receivables assigned to the Factors, and interest is calculated at the applicable EUR LIBOR rate plus a spread. The total amount factored on a non-recourse basis and excluded from accounts receivable was $24.3 million and $27.5 million at December 31, 2018 and December 31, 2017, respectively.

Revolving Credit Agreements

On March 8, 2018, we terminated the revolving credit agreement entered into in December 2014 (the "2014 Revolver") and entered into a $1.0 billion revolving credit agreement maturing on March 8, 2023 (the "2018 Revolver"). There were no borrowings outstanding under the 2018 Revolver as of December 31, 2018 or under the 2014 Revolver as of December 31, 2017.

Perrigo Company plc - Item 7
Financial Condition, Liquidity and Capital Resources

Term Loans, Notes and Bonds

Total Term Loans, Notes and Bonds outstanding are summarized as follows (in millions):

			December 31, 2018	December 31, 2017
Term loans				
*	2018 Term loan due March 8, 2020		$ 351.3	$ —
*	2014 Term loan due December 5, 2019		—	420.0
	Total term loans		351.3	420.0
Notes and bonds				
	Coupon	**Due**		
*	5.000%	May 23, 2019	137.6	144.0
	3.500%	March 15, 2021	280.4	280.4
	3.500%	December 15, 2021	309.6	309.6
*	5.105%	July 19, 2023	154.9	162.0
	4.000%	November 15, 2023	215.6	215.6
	3.900%	December 15, 2024	700.0	700.0
	4.375%	March 15, 2026	700.0	700.0
	5.300%	November 15, 2043	90.5	90.5
	4.900%	December 15, 2044	303.9	303.9
	Total notes and bonds		$ 2,892.5	$ 2,906.0

* Debt denominated in euros subject to fluctuations in the euro-to-U.S. dollar exchange rate.

Debt Repayments

During the year ended December 31, 2018, we made $51.5 million in scheduled principal payments. During the year ended December 31, 2017, we reduced our outstanding debt by $2.6 billion through a variety of early redemption and tender offer transactions.

We are in compliance with all covenants under our debt agreements as of December 31, 2018.

Credit Ratings

Our credit ratings on December 31, 2018 were Baa3 (stable) and BBB- (stable) by Moody's Investors Service and Standard and Poor's Rating Services, respectively.

Credit rating agencies review their ratings periodically and, therefore, the credit rating assigned to us by each agency may be subject to revision at any time. Accordingly, we are not able to predict whether current credit ratings will remain as disclosed above. Factors that can affect our credit ratings include changes in operating performance, the economic environment, our financial position, and changes in business strategy. If changes in our credit ratings were to occur, they could impact, among other things, future borrowing costs, access to capital markets, and vendor financing terms.

Off-Balance Sheet Arrangements
We have no off-balance sheet arrangements that have a material current effect or that are reasonably likely

to have a material future effect on our financial condition, changes in financial condition, net sales or expenses, results of operations, liquidity, capital expenditures, or capital resources. We acquire and collaborate on potential products still in development and enter into R&D arrangements with third parties that often require milestone payments to the third-party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required contingent upon the successful achievement of an important point in the development life cycle of the product. Because of the contingent nature of these payments, they are not included in our table of contractual obligations below.

Contractual Obligations

Our enforceable and legally binding obligations as of December 31, 2018 are set forth in the following table. Some of the amounts included in this table are based on management's estimates and assumptions about these obligations, including the duration, the possibility of renewal, anticipated actions by third parties and other factors. Because these estimates and assumptions are necessarily subjective, the enforceable and legally binding obligations actually paid in future periods may vary from the amounts reflected in the table (in millions):

	Payment Due				
	2019	2020-2021	2022-2023	After 2023	Total
Short and long-term debt [1]	$313.5	$ 1,113.9	$ 557.3	$2,297.1	$4,281.8
Capital lease obligations	1.1	1.5	0.7	—	3.3
Purchase obligations [2]	754.0	4.2	0.1	—	758.3
Operating leases [3]	39.3	56.9	26.6	33.0	155.8
Other contractual liabilities reflected on the consolidated balance sheets:					
Deferred compensation and benefits [4]	—	—	—	110.4	110.4
Other [5]	74.3	9.0	4.3	—	87.6
Total	$1,182.2	$ 1,185.5	$ 589.0	$2,440.5	$5,397.2

(1) Short-term and long-term debt includes interest payments, which were calculated using the effective interest rate at December 31, 2018.
(2) Consists of commitments for both materials and services.
(3) Used in normal course of business, principally for warehouse facilities and computer equipment.
(4) Includes amounts associated with non-qualified plans related to deferred compensation, executive retention and post employment benefits. Of this amount, we have funded $31.5 million, which is recorded in Other non-current assets on the balance sheet. These amounts are assumed payable after five years, although certain circumstances, such as termination, would require earlier payment.
(5) Primarily includes consulting fees, legal settlements, contingent consideration obligations, restructuring accruals, insurance obligations, and electrical and gas purchase contracts, which were accrued in Other current liabilities and Other non-current liabilities at December 31, 2018 for all years.

We fund our U.S. qualified profit-sharing and investment plan in accordance with the Employee Retirement Income Security Act of 1974 regulations for the minimum annual required contribution and Internal Revenue Service regulations for the maximum annual allowable tax deduction. We are committed to making the required minimum contributions, which we expect to be approximately $22.8 million over the next 12 months. Future contributions are dependent upon various factors, including employees' eligible compensation, plan participation and changes, if any, to current funding requirements. Therefore, no amounts were included in the Contractual Obligations table above. We generally expect to fund all future contributions with cash flows from operating activities.

As of December 31, 2018, we had approximately $463.9 million of liabilities for uncertain tax positions, including interest and penalties. These unrecognized tax benefits have been excluded from the Contractual Obligations table above due to uncertainty as to the amounts and timing of settlement with taxing authorities.

Net deferred income tax liabilities were $281.1 million as of December 31, 2018. This amount is not included in the Contractual Obligations table above because we believe this presentation would not be meaningful. Net deferred income tax liabilities are calculated based on temporary differences between the tax basis of assets and liabilities and their book basis, which will result in taxable amounts in future years when the book basis is settled. The results of these calculations do not have a direct connection with the

amount of cash taxes to be paid in any future periods. As a result, scheduling net deferred income tax liabilities as payments due by period could be misleading because this scheduling would not relate to liquidity needs.

Perrigo Company plc - Item 7
Critical Accounting Estimates

Critical Accounting Estimates

The determination of certain amounts in our financial statements requires the use of estimates. These estimates are based upon our historical experiences combined with management's understanding of current facts and circumstances. Although the estimates are considered reasonable based on the currently available information, actual results could differ from the estimates we have used. Management considers the below accounting estimates to require the most judgment and to be the most critical in the preparation of our financial statements. These estimates are reviewed by the Audit Committee.

Revenue Recognition

Net product sales include estimates of variable consideration for which accruals and allowances are established. Variable consideration for product sales consists primarily of chargebacks, rebates, other incentive programs, and related administrative fees recorded on the Consolidated Balance Sheets as Accrued customer programs, and sales returns and shelf stock allowances recorded on the Consolidated Balance Sheets as a reduction to Accounts receivable. Where appropriate, these estimates take into consideration a range of possible outcomes in which relevant factors, such as historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns, are either probability-weighted to derive an estimate of expected value or the estimate reflects the single most likely outcome. Overall, these reserves reflect the best estimates of the amount of consideration to which we are entitled based on the terms of the contract. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from the estimates, these estimates are adjusted, which would affect revenue and earnings in the period such variances become known.

The aggregate gross-to-net adjustments related to RX products can exceed 50% of the segment's gross sales. In contrast, the aggregate gross-to-net adjustments related to CHCA and CHCI typically do not exceed 10% of the segment's gross sales. The following table summarizes the activity in Accrued customer programs and allowance accounts on the Consolidated Balance Sheets (in millions):

	RX				**All Other Segments** *	
	Chargebacks	Medicaid Rebates	Sales Returns and Shelf Stock Allowances	Admin. Fees and Other Rebates	Rebates and Other Allowances	Total
Balance at December 31, 2016	$217.0	$ 24.6	$ 77.1	$ 34.6	$ 131.0	$484.3
Foreign currency translation adjustments	—	—	—	—	0.1	0.1
Provisions / Adjustments	1,564.3	45.1	43.7	113.8	281.2	2,048.1
Credits / Payments	(1,551.4)	(32.9)	(44.6)	(105.2)	(286.1)	(2,020.2)
Balance at December 31, 2017	$229.9	$ 36.8	$ 76.2	$ 43.2	$ 126.2	$512.3
Foreign currency translation adjustments	—	—	—	—	(3.5)	(3.5)
Provisions / Adjustments	1,754.4	58.3	17.0	99.6	270.3	2,199.6
Credits / Payments	(1,718.3)	(58.7)	(22.2)	(98.3)	(276.1)	(2,173.6)
Balance at December 31, 2018	$266.0	$ 36.4	$ 71.0	$ 44.5	$ 116.9	$534.8

*Primarily and .

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Perrigo Company plc - Item 7
Critical Accounting Estimates

Chargebacks

We market and sell U.S. Rx pharmaceutical products directly to wholesalers, distributors, warehousing pharmacy chains, and other direct purchasing groups. We also market products indirectly to independent pharmacies, non-warehousing chains, managed care organizations, and group purchasing organizations, (collectively referred to as "indirect customers"). In addition, we enter into agreements with some indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide chargeback credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price. The accrual for chargebacks includes an estimate for outstanding claims that occurred but for which the related claim has not yet been paid, and an estimate for future claims that will be made when the wholesaler inventory is sold to the indirect customer. This estimate is based on historical chargeback experience, which includes sell-through levels by wholesalers to retailers, and confirmed wholesaler inventory levels. We regularly assess current pricing dynamics and wholesaler inventory levels to ensure the liability for future chargebacks is fairly stated.

Medicaid Rebates

We participate in certain qualifying U.S. federal and state government programs whereby discounts and rebates are provided to participating government entities. Medicaid rebates are amounts owed based upon contractual agreements or legal requirements with public sector (Medicaid) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. Medicaid reserves are based on expected payments, which are driven by patient usage, contract performance, and field inventory that will be subject to a Medicaid rebate. Medicaid rebates are typically billed up to 180 days after the product is shipped, but can be billed as many as 270 days after the quarter in which the product is dispensed to the Medicaid participant. As a result, our Medicaid rebate provision includes an estimate of outstanding claims for end-customer sales that occurred but for which the related claim has not been billed, and an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants. Our calculation also requires other estimates, such as estimates of sales mix, to determine which sales are subject to rebates and the amount of such rebates. Our rebates are reviewed on a monthly basis against actual claims data to ensure the liability is fairly stated.

Returns and Shelf Stock Allowances

We maintain a return policy that allows our customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. The majority of our product returns are the result of product dating, which falls within the range set by our policy, and are settled through the issuance of a credit to the customer. Our estimate of the provision for returns is based upon our historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which our customers may return product. The period is based on the shelf life of the products at the time of shipment. Additionally, when establishing our reserves, we consider factors such as levels of inventory in the distribution channel, product dating and expiration period, size and maturity of the market prior to a product launch, entrance into the market of additional competition, and changes in formulations.

Shelf stock allowances are credits issued to reflect changes in the selling price of a product and are based upon estimates of the amount of product remaining in a customer's inventory at the time of the anticipated price change. In many cases, the customer is contractually entitled to such a credit. The allowances for shelf stock adjustments are based on specified terms with certain customers, estimated launch dates of competing products, and estimated changes in market price.

RX Administrative Fees and Other Rebates

Rebates or administrative fees are offered to certain wholesale customers, group purchasing organizations, and end-user customers. Settlement of rebates and fees generally may occur from one to 15 months from the date of sale. We provide a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Estimates used to establish the provision include level of wholesaler inventories, contract sales volumes, and average contract pricing.

CHCA and CHCI Rebates and Other Allowances

In the CHCA and CHCI segments, we offer certain customers a volume incentive rebate if specific levels of product purchases are made during a specified period. The accrual for rebates is based on contractual agreements and estimated levels of purchasing. In addition, we have a reserve for product returns, primarily related to damaged and unsaleable products. We also have agreements with certain customers to cover promotional activities related to our products such as coupon programs, new store allowances, and product displays. The accrual for these activities is based on customer agreements and is established at the time product revenue is recognized.

Allowances for customer-related programs are generally recorded at the time of sale based on the estimates and methodologies described above. We continually monitor product sales provisions and re-evaluate these estimates as additional information becomes available, which includes, among other things, an assessment of current market conditions, trade inventory levels, and customer product mix. We make adjustments to these provisions at the end of each reporting period to reflect any such updates to the relevant facts and circumstances.

Income Taxes

Our tax rate is subject to adjustment over the balance of the year due to, among other things, 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 (for example, proposals for fundamental U.S. and international tax reform); changes in U.S. generally accepted accounting principles; expiration of or the inability to renew tax rulings or tax holiday incentives; and the repatriation of earnings with respect to which we have not previously provided taxes.

Although we believe that our tax estimates are reasonable and that we prepare our tax filings 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 and/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, and/or interest assessments (refer to Item 8. Note 14).

Legal Contingencies

We are involved in product liability, patent, commercial, regulatory and other legal proceedings that arise in the normal course of business. We record a liability when a loss is considered probable and the amount can be reasonably estimated. If the reasonable estimate of a probable loss is a range and no amount within that range is a better estimate, the minimum amount in the range is accrued. If a loss is not probable or a probable loss cannot be reasonably estimated, no liability is recorded. We have established reserves for certain of our legal matters. We also separately record any insurance recoveries that are probable to occur (refer to Item 8. Note 16).

Change in Financial Assets

We valued our contingent milestone payments from Royalty Pharma using a modified Black-Scholes Option Pricing Model ("BSOPM"). Key inputs in the BSOPM are the estimated volatility and rate of return of royalties on global net sales of Tysabri® that are received by Royalty Pharma until the contingent milestones are resolved. Volatility and the estimated fair value of the milestones have a positive relationship such that higher volatility translates to a higher estimated fair value of the contingent milestone payments. We assess volatility and rate of

return inputs quarterly by analyzing certain market volatility benchmarks and the risk associated with Royalty Pharma achieving the underlying projected royalties. The table below represents the volatility and rate of return:

	Year Ended December 31, 2018	December 31, 2017	
Volatility	30.0%	30.0	%
Rate of return	8.05%	8.07	%

In order for us to receive the 2020 milestone payment, Royalty Pharma contingent payments for Tysabri® sales in 2020 must exceed $351.0 million. If Royalty Pharma contingent payments for Tysabri® sales do not meet the prescribed threshold in 2020, we will write off the $73.2 million asset as an expense. If the prescribed threshold is exceeded, we will increase the asset to $400.0 million and recognize income of $326.8 million in Change in financial assets on the Consolidated Statements of Operations (refer to Item 8. Note 7).

Goodwill

Goodwill represents amounts paid for an acquisition in excess of the fair value of net assets received. We have six reporting units subject to impairment testing annually, on the first day of the fourth quarter, or more frequently if events suggest an impairment may exist. We had triggering events during the third quarter of the year ended December 31, 2018 and therefore performed an interim impairment test in the third quarter of 2018, followed by our annual test performed as of September 30, 2018, the first day of our fourth quarter. The test for impairment requires us to make several estimates about fair value, most of which are based on projected future cash flows and market valuation multiples. The estimates associated with the goodwill impairment tests are considered critical due to the judgments required in determining fair value amounts, including projected future cash flows that include assumptions about future performance. The discount rates used in testing each of our reporting units' goodwill for impairment during our interim and annual testing were based on the weighted average cost of capital determined for each of our reporting units and ranged from 8.5% to 13.8%. Perpetual growth rates for each reporting unit ranged from 2.0% to 3.0%. Changes in these estimates may result in the recognition of an impairment loss. We recorded goodwill impairment losses of $136.7 million related to animal health and $1.1 billion related to BCH and Specialty Sciences during the years ended December 31, 2018 and December 31, 2016, respectively, which was recorded in Impairment charges on the Consolidated Statements of Operations. No goodwill impairments were recorded during the year ended December 31, 2017.

During our annual goodwill testing as of September 30, 2018, we determined the fair value of the BCH reporting unit included in the CHCI segment was less than 10.0% higher than its net book value. We performed additional quantitative analysis during the three months ended December 31, 2018 and concluded that the fair value of the BCH reporting unit remained less than 10% higher than its net book value as of December 31, 2018. As a result of the relatively narrow margin between fair value and net book value during the three months ended December 31, 2018, this reporting unit is inherently at a higher risk for future impairments if it experiences deterioration in business performance or market multiples or increases in discount rates.

The discounted cash flow forecasts used for the BCH reporting unit include assumptions about future activity levels in the near term and longer-term. If growth in this reporting unit is lower than expected, we may experience deterioration in our cash flow forecasts that may indicate goodwill in the reporting unit may be impaired in future impairment tests. We continue to monitor the progress and assess the reporting unit for potential impairment should impairment indicators arise, as applicable, and at least annually during our fourth quarter impairment testing.

Management performed sensitivity analyses on the discounted cash flow valuations that were prepared to estimate the enterprise values of each reporting unit. Discount rates were increased and decreased by increments of 50 basis points, up to cumulative increases and decreases of 250 basis points. Perpetual revenue growth rates were increased and decreased by increments of 25 or 50 basis points, up to cumulative increases and decreases of 100 basis points.

A 100 basis point increase in the discount rate, or different combinations of changes in discount rate and the perpetual revenue growth rate, would indicate potential impairment for this reporting unit. Based on the sensitivity of the discount rate assumption on the BCH reporting unit analysis, an increase in the discount rate over the next twelve months could negatively impact the estimated fair value of this reporting unit and lead to a future impairment. Certain macroeconomic factors which are not controlled by the reporting unit, such as rising inflation or interest rates, could cause an increase in the discount rate to occur. Deterioration in BCH performance over the next twelve months, such as lower than expected revenue or profitability that has a sustained impact on future periods, could also represent potential indicators of impairment requiring further impairment analysis.

See Item 8. Note 4 and Note 7 for further information.

Recently Issued Accounting Standards Pronouncements

See Item 8. Note 1 for information regarding recently issued accounting standards.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Exchange Risk

We are a global company with operations primarily throughout North America, Europe, Australia, Mexico, and Israel. We transact business in each location's local currency and in foreign currencies, thereby creating exposures to changes in exchange rates. Our largest exposure is the movement of the U.S. dollar relative to the euro. In addition, our U.S. operations continue to expand their export business, primarily in Canada, China, and Europe, and are subject to fluctuations in the respective exchange rates relative to the U.S. dollar. A large portion of the sales of our Israeli operations is in foreign currencies, primarily U.S. dollars and euros, while these operations largely incur costs in their local currency. Further, a portion of Biogen's global sales of Tysabri® are denominated in local currencies, creating exposures to changes in exchange rates relative to the U.S. dollar and thereby impacting the amount of U.S. dollar royalties necessary to achieve our contingent payment threshold in 2020.

Due to different sales and cost structures, certain segments experience a negative impact and certain segments a positive impact as a result of changes in exchange rates. We estimate the translation effect of a ten percent devaluation of the U.S. dollar relative to the other foreign currencies in which we transact business would have increased operating income of our non-U.S. operating units by approximately $33.5 million for the year ended December 31, 2018. This sensitivity analysis has inherent limitations. The analysis disregards the possibility that rates of multiple foreign currencies will not always move in the same direction relative to the value of the U.S. dollar over time and does not account for foreign exchange derivatives that we utilize to mitigate fluctuations in exchange rates.

In addition, we enter into certain purchase commitments for materials that, although denominated in U.S. dollars, are linked to foreign currency valuations. These commitments generally contain a range for which the price of materials may fluctuate over time given the value of a foreign currency.

The translation of the assets and liabilities of our non-U.S. dollar denominated operations is made using local currency exchange rates as of the end of the year. Translation adjustments are not included in determining net income but are disclosed in Accumulated Other Comprehensive Income ("AOCI") within shareholders' equity on the Consolidated Balance Sheets until a sale or substantially complete liquidation of the net investment in the subsidiary takes place. In certain markets, we could recognize a significant gain or loss related to unrealized cumulative translation adjustments if we were to exit the market and liquidate our net investment. As of December 31, 2018, cumulative net currency translation adjustments increased shareholders' equity by$104.5 million.

We monitor and strive to manage risk related to foreign currency exchange rates. Exposures that cannot be naturally offset within a local entity to an immaterial amount are often hedged with foreign exchange derivatives or netted with offsetting exposures at other entities. We cannot predict future changes in foreign currency movements and fluctuations that could materially impact earnings.

Interest Rate Risk

We are exposed to interest rate changes primarily as a result of interest income earned on our investment of cash on hand and interest expense on borrowings.

We have in the past, and may in the future, enter into certain derivative financial instruments related to the management of interest rate risk, when available on a cost-effective basis. These instruments are managed on a consolidated basis to efficiently net exposures and thus take advantage of any natural offsets. Gains and losses on hedging transactions are offset by gains and losses on the underlying exposures being hedged. We do not use derivative financial instruments for speculative purposes.

See Item 8. Note 9 and Note 1 for further information regarding our derivative instruments and hedging activities.

Perrigo Company plc - Item 8

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS **PAGE NO.**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Perrigo Company plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Perrigo Company plc (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and the financial statement schedule listed in the Index at Item 15(a) (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 27, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2008.

Grand Rapids, Michigan
February 27, 2019

PERRIGO COMPANY PLC
CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions, except per share amounts)

	Year Ended		
	December 31, 2018	**December 31, 2017**	**December 31, 2016**
Net sales	$4,731.7	$ 4,946.2	$ 5,280.6
Cost of sales	2,900.2	2,966.7	3,228.8
Gross profit	1,831.5	1,979.5	2,051.8
Operating expenses			
Distribution	94.2	87.0	88.3
Research and development	218.6	167.7	184.0
Selling	595.7	598.4	665.0
Administration	435.9	461.1	452.2
Impairment charges	224.4	47.5	2,631.0
Restructuring	21.0	61.0	31.0
Other operating expense (income)	5.2	(41.4)	—
Total operating expenses	1,595.0	1,381.3	4,051.5
Operating income (loss)	236.5	598.2	(1,999.7)
Change in financial assets	(188.7)	24.9	2,608.2
Interest expense, net	128.0	168.1	216.6
Other (income) expense, net	6.1	(10.1)	22.7
Loss on extinguishment of debt	0.5	135.2	1.1
Income (loss) before income taxes	290.6	280.1	(4,848.3)
Income tax expense (benefit)	159.6	160.5	(835.5)
Net income (loss)	$131.0	$ 119.6	$ (4,012.8)
Earnings (loss) per share			
Basic	$0.95	$ 0.84	$ (28.01)
Diluted	$0.95	$ 0.84	$ (28.01)
Weighted-average shares outstanding			
Basic	137.8	142.3	143.3
Diluted	138.3	142.6	143.3

See accompanying Notes to Consolidated Financial Statements.

PERRIGO COMPANY PLC
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in millions)

	Year Ended		
	December 31, 2018	December 31, 2017	December 31, 2016
Net income (loss)	$131.0	$ 119.6	$ (4,012.8)
Other comprehensive income (loss):			
Foreign currency translation adjustments	(156.1)	328.5	(63.3)
Change in fair value of derivative financial instruments	(5.7)	9.7	(5.3)
Change in fair value of investment securities	—	(14.1)	8.7
Change in post-retirement and pension liability	(5.7)	10.8	(6.6)
Other comprehensive income (loss), net of tax	(167.5)	334.9	(66.5)
Comprehensive income (loss)	$(36.5)	$ 454.5	$ (4,079.3)

See accompanying Notes to Consolidated Financial Statements.

PERRIGO COMPANY PLC
CONSOLIDATED BALANCE SHEETS
(in millions, except per share amounts)

	December 31, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 551.1	$ 678.7
Accounts receivable, net of allowance for doubtful accounts of $6.4 and $6.2, respectively	1,073.1	1,130.8
Inventories	878.0	806.9
Prepaid expenses and other current assets	400.0	203.2
Total current assets	2,902.2	2,819.6
Property, plant and equipment, net	829.1	833.1
Goodwill and indefinite-lived intangible assets	4,029.1	4,265.7
Definite-lived intangible assets, net	2,858.9	3,290.5
Deferred income taxes	1.2	10.4
Other non-current assets	362.9	409.5
Total non-current assets	8,081.2	8,809.2
Total assets	$ 10,983.4	$ 11,628.8
Liabilities and Shareholders' Equity		
Accounts payable	$ 474.9	$ 450.2
Payroll and related taxes	132.1	148.8
Accrued customer programs	442.4	419.7
Accrued liabilities	201.3	230.8
Accrued income taxes	96.5	116.1
Current indebtedness	190.2	70.4
Total current liabilities	1,537.4	1,436.0
Long-term debt, less current portion	3,052.2	3,270.8
Deferred income taxes	282.3	321.9
Other non-current liabilities	443.4	429.5
Total non-current liabilities	3,777.9	4,022.2
Total liabilities	5,315.3	5,458.2
Commitments and contingencies - Refer to Note 16		
Shareholders' equity		
Controlling interests:		
Preferred shares, $0.0001 par value per share, 10 shares authorized	—	—
Ordinary shares, €0.001 par value per share, 10,000 shares authorized	7,421.7	7,892.9
Accumulated other comprehensive income	84.6	253.1
Retained earnings (accumulated deficit)	(1,838.3)	(1,975.5)
Total controlling interests	5,668.0	6,170.5
Noncontrolling interest	0.1	0.1
Total shareholders' equity	5,668.1	6,170.6
Total liabilities and shareholders' equity	$ 10,983.4	$ 11,628.8

Supplemental Disclosures of Balance Sheet Information

Preferred shares, issued and outstanding	—	—
Ordinary shares, issued and outstanding	135.9	140.8

See accompanying Notes to Consolidated Financial Statements.

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PERRIGO COMPANY PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)

	Year Ended December 31, 2018	December 31, 2017	December 31, 2016
Cash Flows From (For) Operating Activities			
Net income	$131.0	$ 119.6	$ (4,012.8)
Adjustments to derive cash flows:			
Depreciation and amortization	423.6	444.8	457.0
Share-based compensation	37.7	43.8	23.0
Impairment charges	224.4	47.5	2,631.0
Change in financial assets	(188.7)	24.9	2,608.2
Loss on extinguishment of debt	0.5	135.2	1.1
Restructuring charges	21.0	61.0	31.0
Deferred income taxes	(17.9)	(48.9)	(990.9)
Amortization of debt premium	(8.1)	(22.4)	(24.7)
Other non-cash adjustments, net	(11.1)	(2.7)	33.5
Subtotal	612.4	802.8	756.4
Increase (decrease) in cash due to:			
Accounts receivable	21.0	3.2	(0.6)
Inventories	(98.6)	(16.0)	100.7
Accounts payable	28.8	(39.6)	(75.7)
Payroll and related taxes	(34.5)	(27.4)	(41.1)
Accrued customer programs	25.5	34.6	(13.9)
Accrued liabilities	(20.9)	(47.8)	(79.5)
Accrued income taxes	68.1	(6.1)	20.9
Other, net	(8.8)	(4.8)	(12.3)
Subtotal	(19.4)	(103.9)	(101.5)
Net cash from (for) operating activities	593.0	698.9	654.9
Cash Flows From (For) Investing Activities			
Proceeds from royalty rights	13.7	87.3	353.7
Acquisitions of businesses, net of cash acquired	—	(0.4)	(427.4)
Asset acquisitions	(35.6)	—	(65.1)
Purchase of investment securities	(7.5)	—	—
Proceeds from sale of securities	—	—	4.5
Additions to property, plant and equipment	(102.6)	(88.6)	(106.2)
Net proceeds from sale of business and other assets	5.2	154.6	69.1
Proceeds from sale of the Tysabri® financial asset	—	2,200.0	—
Other investing, net	—	(14.8)	(3.6)
Net cash from (for) investing activities	(126.8)	2,338.1	(175.0)
Cash Flows From (For) Financing Activities			
Borrowings (repayments) of revolving credit agreements and other financing, net	(4.4)	6.8	(802.5)
Issuances of long-term debt	431.0	—	1,190.3
Payments on long-term debt	(482.5)	(2,611.0)	(559.2)
Premium on early debt retirement	—	(116.1)	(0.6)
Deferred financing fees	(2.4)	(4.8)	(2.8)

Issuance of ordinary shares	1.3	0.7	8.3
Equity issuance costs	—	—	(10.3)
Repurchase of ordinary shares	(400.0)	(191.5)	—
Cash dividends	(104.9)	(91.1)	(83.2)
Other financing, net	(10.0)	2.3	(8.7)
Net cash from (for) financing activities	(571.9)	(3,004.7)	(268.7)
Effect of exchange rate changes on cash and cash equivalents	(21.9)	24.1	(6.7)
Net increase (decrease) in cash and cash equivalents	(127.6)	56.4	204.5
Cash and cash equivalents, beginning of period	678.7	622.3	417.8
Cash and cash equivalents, end of period	$551.1	$ 678.7	$ 622.3

	Year Ended		
	December 31, 2018	December 31, 2017	December 31, 2016
Supplemental Disclosures of Cash Flow Information			
Cash paid/received during the year for:			
Interest paid	$133.8	$ 187.6	$ 205.1
Interest received	$5.0	$ 9.3	$ 1.2
Income taxes paid	$144.2	$ 186.9	$ 139.5
Income taxes refunded	$5.1	$ 3.6	$ 9.3

See accompanying Notes to Consolidated Financial Statements.

Perrigo Company plc - Item 8

PERRIGO COMPANY PLC
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(in millions, except per share amounts)

	Ordinary Shares Issued		Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total
	Shares	Amount			
Balance at December 31, 2015	143.1	$8,142.6	$ (15.3)	$ 1,980.1	$10,107.4
Net loss	—	—	—	(4,012.8)	(4,012.8)
Other comprehensive loss	—	—	(66.5)	—	(66.5)
Issuance of ordinary shares under:					
Stock options	0.2	8.3	—	—	8.3
Restricted stock plan	0.2	—	—	—	—
Compensation for stock options	—	5.0	—	—	5.0
Compensation for restricted stock	—	18.0	—	—	18.0
Cash dividends, $0.58 per share	—	(20.8)	—	(62.4)	(83.2)
Tax effect from stock transactions	—	(1.5)	—	—	(1.5)
Shares withheld for payment of employees' withholding tax liability	(0.1)	(6.3)	—	—	(6.3)
Equity issuance costs	—	(10.3)	—	—	(10.3)
Balance at December 31, 2016	143.4	8,135.0	(81.8)	(2,095.1)	5,958.1
Net income	—	—	—	119.6	119.6
Other comprehensive income	—	—	334.9	—	334.9
Issuance of ordinary shares under:					
Stock options	0.1	0.7	—	—	0.7
Restricted stock plan	0.1	—	—	—	—
Compensation for stock options	—	8.9	—	—	8.9
Compensation for restricted stock	—	34.9	—	—	34.9
Cash dividends, $0.64 per share	—	(91.1)	—	—	(91.1)
Shares withheld for payment of employees' withholding tax liability	(0.1)	(4.0)	—	—	(4.0)
Repurchases of ordinary shares	(2.7)	(191.5)	—	—	(191.5)
Balance at December 31, 2017	140.8	7,892.9	253.1	(1,975.5)	6,170.5
Adoption of new accounting standards	—	—	(1.0)	6.2	5.2
Net income	—	—	—	131.0	131.0
Other comprehensive income	—	—	(167.5)	—	(167.5)
Issuance of ordinary shares under:					
Stock options	0.1	1.3	—	—	1.3
Restricted stock plan	0.2	—	—	—	—
Compensation for stock options	—	8.1	—	—	8.1
Compensation for restricted stock	—	29.6	—	—	29.6
Cash dividends, $0.76 per share	—	(104.9)	—	—	(104.9)
Repurchases of ordinary shares	(5.1)	(400.0)	—	—	(400.0)
Shares withheld for payment of employees' withholding tax liability	(0.1)	(5.3)	—	—	(5.3)
Balance at December 31, 2018	135.9	$7,421.7	$ 84.6	$ (1,838.3)	$5,668.0

See accompanying Notes to Consolidated Financial Statements.

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

General Information

The Company

Perrigo Company plc was incorporated under the laws of Ireland on June 28, 2013 and became the successor registrant of Perrigo Company, a Michigan corporation, on December 18, 2013 in connection with the acquisition of Elan Corporation, plc ("Elan"). 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.

We are a leading global healthcare company that has been delivering value to our customers and consumers by providing Quality Affordable Healthcare Products®. Founded in 1887 as a packager of home remedies, we have built a unique business model that is best described as the convergence of a fast-moving consumer goods company, a high-quality pharmaceutical manufacturing organization and a world-class supply chain network. We are one of the world's largest manufacturers of over-the-counter (“OTC”) healthcare products and suppliers of infant formulas for the store brand market. We are also a leading provider of branded consumer health and wellness products throughout Europe and a leading producer of generic prescription pharmaceutical topical products such as creams, lotions, gels, and nasal sprays ("extended topicals"). We are headquartered in Ireland and sell our products primarily in the U.S. and Europe, as well as in other markets, including Israel, Mexico, Australia, and Canada.

Basis of Presentation

Our fiscal year begins on January 1 and ends on December 31 of each year. We end 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.

Segment Reporting

Our operating and reportable segments are as follows:

- **Consumer Healthcare Americas** (**"CHCA")**, comprises our U.S., Mexico and Canada consumer healthcare business (OTC, contract manufacturing, infant formula and animal health categories).
- **Consumer Healthcare International** (**"CHCI")**, comprises our branded consumer healthcare business primarily in Europe and our consumer focused businesses in the United Kingdom ("U.K."), Australia, and Israel. This segment also includes our U.K. liquid licensed products business.
- **Prescription Pharmaceuticals** (**"RX")**, comprises our U.S. Prescription Pharmaceuticals business.

Our segments reflect the way in which our management makes operating decisions, allocates resources and manages the growth and profitability of the Company.

Principles of Consolidation

The consolidated financial statements include our accounts and accounts of all majority-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Unconsolidated Variable Interest Entities

We have research and development ("R&D") arrangements with certain biotechnology companies that we determined to be variable interest entities ("VIEs"). We did not consolidate the VIEs in our financial statements because we lack the power to direct the activities that most significantly impact their economic performance and thus are not considered the primary beneficiaries of these entities. These arrangements provide us with certain rights and obligations to purchase product candidates from the VIEs, dependent upon the outcome of the development activities.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions, which affect the reported earnings, financial position and various disclosures. Although the estimates are considered reasonable, actual results could differ from the estimates.

Non-U.S. Operations

We translate our non-U.S. dollar-denominated operations' assets and liabilities into U.S. dollars at current rates of exchange as of the balance sheet date and income and expense items at the average exchange rate for the reporting period. Translation adjustments resulting from exchange rate fluctuations are recorded in the cumulative translation account, a component of Accumulated other comprehensive income (loss) ("AOCI"). Gains or losses from foreign currency transactions are included in Other (income) expense, net.

Revenue

Product Revenue

We generally recognize product revenue for our contract performance obligations at a point in time, typically upon shipment or delivery of products to customers. For point in time customers for which control transfers on delivery to the customer due to free on board destination terms ("FOB"), an adjustment is recorded to defer revenue recognition over an estimate of days until control transfers at the point of delivery. Where we recognize revenue at a point in time, the transfer of title is the primary indicator that control has transferred. In other limited instances, primarily relating to those contracts that relate to contract manufacturing performed for our customers and certain store branded products, control transfers as the product is manufactured. Control is deemed to transfer over time for these contracts as the product does not have an alternative use and we have a contractual right to payment for performance completed to date. Revenue for contract manufacturing contracts is recognized over the transfer period using an input method that measures progress towards completion of the performance obligation as costs are incurred. For store branded product revenue recognized over time, an output method is used to recognize revenue when production of a unit is completed because product customization occurs when the product is packaged as a finished good under the store brand label of the customer.

Net product sales include estimates of variable consideration for which accruals and allowances are established. Variable consideration for product sales consists primarily of chargebacks, rebates, and

administrative fees and other incentive programs recorded on the Consolidated Balance Sheets as Accrued customer programs, and sales returns and shelf stock allowances recorded on the Consolidated Balance Sheets as a reduction to Accounts receivable. Where appropriate, these estimates take into consideration a range of possible outcomes in which relevant factors, such as historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns, are either probability weighted to derive an estimate of expected value or the estimate reflects the single most likely outcome. Overall, these reserves reflect the best estimates of the amount of consideration to which we are entitled based on the terms of the contract. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from the estimates, these estimates are adjusted, which would affect revenue and earnings in the period such variances become known. Accrued customer programs and allowances were $534.8 million and $512.3 million at December 31, 2018 and December 31, 2017, respectively.

Other Revenue Policies

We receive payments from our customers based on billing schedules established in each contract. Amounts are recorded as accounts receivable when our right to consideration is unconditional. In most cases, the timing of the unconditional right to payment aligns with shipment or delivery of the product and the recognition of revenue; however, for those customers where revenue is recognized at a time prior to shipment or delivery due to over time revenue recognition, a contract asset is recorded and is reclassified to accounts receivable when it becomes unconditional under the contract upon shipment or delivery to the customer.

Our performance obligations are generally expected to be fulfilled in less than one year. Therefore, we do not provide quantitative information about remaining performance obligations.

We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised products to the customer will be one year or less, which is the case with substantially all customers.

Taxes collected from customers relating to product sales and remitted to governmental authorities are excluded from revenue.

Shipping and handling costs billed to customers are included in Net sales. Conversely, shipping and handling expenses we incur are included in Cost of sales.

Cash and Cash Equivalents

Cash and cash equivalents consist primarily of demand deposits and other short-term investments with maturities of three months or less at the date of purchase. The carrying amount of cash and cash equivalents approximates its fair value.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the first-in first-out method. Costs include material and conversion costs. Inventory related to R&D is expensed when it is determined the materials have no alternative future use.

We maintain reserves for estimated obsolete or unmarketable inventory based on the difference between the cost of the inventory and its estimated net realizable value. In estimating the reserves, management considers factors such as excess or slow-moving inventories, product expiration dating, products on quality hold, current and future customer demand and market conditions. Changes in these conditions may result in additional reserves (refer to Note 6).

Investments

Fair Value Method Investments

Equity investments in which we own less than a 20% interest and cannot exert significant influence are recorded at fair value with unrealized gains and losses included in net income. For equity investments without readily determinable fair values, we may use the Net Asset Value ("NAV") per share as a practical expedient to measure the fair value, if eligible. If the NAV practical expedient cannot be applied, we may elect to use a measurement alternative until the investment’s fair value becomes readily determinable. Under the alternative method, the equity investments are accounted for at cost, less any impairment, plus or minus changes resulting from observable price changes in an orderly transaction for an identical or similar investment of the same issuer.

Equity Method Investments

The equity method of accounting is used for unconsolidated entities over which we have significant influence; generally, this represents ownership interests of at least 20% and not more than 50%. Under the equity method of accounting, we record the investments at carrying value and adjust for a proportionate share of the

profits and losses of these entities each period. We evaluate our equity method investments for recoverability. If we determine that a loss in the value of an investment is other than temporary, the investment is written down to its estimated fair value. Evaluations of recoverability are based primarily on projected cash flows.

For more information on our investments, refer to Note 8.

Derivative Instruments

We record derivative instruments on the balance sheet on a gross basis as either an asset or liability measured at fair value. Additionally, changes in a derivative's fair value, which are measured at the end of each period, are recognized in earnings unless specific hedge accounting criteria are met. If hedge accounting criteria are met for cash flow hedges, the changes in a derivative’s fair value are recorded in shareholders’ equity as a component of other comprehensive income ("OCI"), net of tax. These deferred gains and losses are recognized in income in the period in which the hedged item and hedging instrument affect earnings. Any ineffective portion of the change in fair value is immediately recognized in earnings.

We are exposed to credit loss in the event of nonperformance by the counterparties on derivative contracts. It is our policy to manage our credit risk on these transactions by dealing only with financial institutions having a long-term credit rating of "A-/A3" or better and by distributing the contracts among several financial institutions to diversify credit concentration risk. Should a counterparty default, our maximum exposure to loss is the asset balance of the instrument. The maximum term of our forward currency exchange contracts is 18 months.

We enter into certain derivative financial instruments, when available on a cost-effective basis, to mitigate our risk associated with changes in interest rates and foreign currency exchange rates as follows:

Interest rate risk management - We are exposed to the impact of interest rate changes through our cash investments and borrowings. We utilize a variety of strategies to manage the impact of changes in interest rates including using a mix of debt maturities along with both fixed-rate and variable-rate debt. In addition, we may enter into treasury-lock agreements and interest rate swap agreements on certain investing and borrowing transactions to manage our exposure to interest rate changes and our overall cost of borrowing.

Foreign currency exchange risk management - We conduct business in several major currencies other than the U.S. dollar and are subject to risks associated with changing foreign exchange rates. Our objective is to reduce cash flow volatility associated with foreign exchange rate changes on a consolidated basis to allow management to focus its attention on business operations. Accordingly, we enter into various contracts that change in value as foreign exchange rates change to protect the value of existing foreign currency assets and liabilities, commitments, and anticipated foreign currency sales and expenses.

All derivative instruments are managed on a consolidated basis to efficiently net exposures and thus take advantage of any natural offsets. Gains and losses related to the derivative instruments are expected to be offset largely by gains and losses on the original underlying asset or liability. We do not use derivative financial instruments for speculative purposes.

Designated derivatives meet hedge accounting criteria, which means the fair value of the hedge is recorded in shareholders' equity as a component of OCI, net of tax. The deferred gains and losses are recognized in income in the period in which the hedged item affects earnings. Any ineffective portion of the change in fair value of the derivative is immediately recognized in earnings. All of our designated derivatives are assessed for hedge effectiveness quarterly.

Non-designated derivatives are those that do not meet hedge accounting criteria. These derivative instruments are adjusted to current market value at the end of each period through earnings. Gains or losses on these instruments are offset substantially by the remeasurement adjustment on the hedged item.

In addition, we have interest rate swap agreements that are contracts to exchange floating rate for fixed rate payments (or vice versa) over the life of the agreement without the exchange of the underlying notional amounts. The notional amounts of the interest rate swap agreements are used to measure interest to be paid or received and do not represent the amount of exposure to credit loss. The differential paid or received on the interest rate swap agreements is recognized as an adjustment to interest expense.

For more information on our derivatives, refer to Note 9.

Property, Plant and Equipment, net

Property, plant and equipment, net is recorded at cost and is depreciated using the straight-line method. Useful lives for financial reporting range from 3 to 20 years for machinery and equipment and 10 to 45 years for buildings. Maintenance and repair costs are charged to earnings, while expenditures that increase asset lives are capitalized. Depreciation expense includes amortization of assets recorded under capital leases and totaled $90.0 million, $95.2 million, and $100.2 million for the years ended December 31, 2018, December 31, 2017, and December 31, 2016, respectively.

We held the following property, plant and equipment, net (in millions):

	December 31, 2018	December 31, 2017
Land	$ 49.0	$ 45.5
Buildings	552.3	514.3
Machinery and equipment	1,079.3	1,078.6
Gross property, plant and equipment	1,680.6	1,638.4
Less accumulated depreciation	(851.5)	(805.3)
Property, plant and equipment, net	$ 829.1	$ 833.1

Goodwill and Intangible Assets

Goodwill

Goodwill represents amounts paid for an acquisition in excess of the fair value of net assets acquired. Goodwill is tested for impairment annually on the first day of our fourth quarter, or more frequently if changes in circumstances or the occurrence of events suggest an impairment exists.

The test for impairment requires us to make several estimates about fair value, most of which are based on projected future cash flows and market valuation multiples. The estimates associated with the goodwill impairment tests are considered critical due to the judgments required in determining fair value amounts, including projected discounted future cash flows. We have six reporting units that are evaluated for impairment. Changes in these estimates may result in the recognition of an impairment loss. Our annual impairment tests were performed as of September 30, 2018 and October 1, 2017 for the years ended December 31, 2018 and December 31, 2017, respectively.

Intangible Assets

We have intangible assets that we have acquired through various business acquisitions and include trademarks, trade names and brands, in-process research and development ("IPR&D"), developed product technology/formulation and product rights, distribution and license agreements, customer relationships and distribution networks, and non-compete agreements. The assets are typically initially valued using the relief from royalty method.

We test indefinite-lived trademarks, trade names, and brands for impairment annually, or more frequently if changes in circumstances or the occurrence of events suggest impairment exists, by comparing the carrying value of the assets to their estimated fair values. An impairment loss is recognized if the carrying amount of the asset is not recoverable and its carrying amount exceeds its fair value.

Definite-lived intangible assets consist of a portfolio of developed product technology/formulation and product rights, distribution and license agreements, customer relationships, non-compete agreements, and certain trademarks, trade names, and brands. The assets are amortized on either a straight-line basis or proportionately to the benefits derived from those relationships or agreements. Useful lives vary by asset type and are determined based on the period over which the intangible asset is expected to contribute directly or indirectly to our future cash flows. We also review all other long-lived assets that have finite lives and that are not held for sale for impairment when indicators of impairment are evident by comparing the carrying value of the assets to their estimated future undiscounted cash flows.

IPR&D assets are recognized at fair value and are classified as indefinite-lived assets until the successful completion or abandonment of the associated R&D efforts. If the associated R&D is completed, the IPR&D asset becomes a definite-lived intangible asset and is amortized over the asset's assigned useful life. If it is abandoned, an impairment loss is recorded.

Goodwill, indefinite-lived intangible asset, and definite-lived intangible asset impairments are recorded in Impairment charges on the Consolidated Statement of Operations. See Note 4 for further information on our goodwill and intangible assets.

Share-Based Awards