ENDO INTERNATIONAL PUBLIC LIMITED COMPANY

Directors' Report and Financial Statements

For the Year Ended December 31, 2018

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DIRECTORS AND OTHER INFORMATION

DIRECTORS	Roger H. Kimmel (United States) Paul Campanelli (United States) Shane M. Cooke Nancy J. Hutson, Ph.D. (United States) Michael Hyatt (United States) Sharad S. Mansukani, M.D. (United States) William P. Montague (United States) Todd B. Sisitsky (United States)
REGISTERED OFFICE	First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4.
REGISTERED NUMBER	534814
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DIRECTORS' REPORT
For the Year Ended December 31, 2018

The directors present their report and audited Consolidated Financial Statements for the year ended December 31, 2018.

Principal Activities

Unless otherwise indicated or required by the context, references throughout to "Endo," the "Group," "we," "our" or "us" refer to financial information and transactions of Endo International plc and its subsidiaries.

Endo International plc is an Ireland-domiciled, global specialty pharmaceutical company focused on generic and branded pharmaceuticals. We aim to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of generic and branded drugs to meet patients' needs. Endo International plc was incorporated in Ireland in 2013 as a private limited company and re-registered effective February 18, 2014 as a public limited company.

Our ordinary shares are traded on the NASDAQ Global Market (NASDAQ) under the ticker symbol "ENDP." References throughout to "ordinary shares" refer to Endo International plc's ordinary shares, 1,000,000,000 authorized, par value $0.0001 per share. In addition, we have 4,000,000 euro deferred shares outstanding, par value of $0.01 each.

Our global headquarters are located at Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland (telephone number: 011-353-1-268-2000) and our U.S. headquarters are located at 1400 Atwater Drive, Malvern, Pennsylvania 19355 (telephone number: 484-216-0000).

Across all of our businesses, we generated total turnover of $2.95 billion and $3.47 billion in 2018 and 2017, respectively.

Our focus is on pharmaceutical products and we target areas where we believe we can build leading positions. We use a differentiated operating model based on a lean and nimble structure, the rational allocation of capital and an emphasis on high-value research and development (R&D) targets. While our primary focus is on organic growth, we evaluate and, where appropriate, execute on opportunities to expand through the acquisition of products and companies in areas that we believe serve patients and customers while offering attractive growth characteristics and margins. We believe our operating model and the execution of our corporate strategy will enable us to create shareholder value over the long-term.

For branded products, we seek to develop, acquire or license products that have inherent scientific, regulatory, legal and technical complexities and market such products under recognizable brand names that are trademarked. For United States (U.S.) products we develop, after the completion of required clinical trials and testing, we seek approvals from regulatory bodies such as through the submission of New Drug Applications (NDAs) or Biologics License Applications (BLAs) to the U.S. Food and Drug Administration (FDA). In the U.S., upon approval, patents included in the applications are listed in a publication referred to as the Orange Book. We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes, trade secrets, know-how, innovations and all of our intellectual property are important to our business and achieving a competitive position. However, there can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition. Additional information is included throughout this Directors' Report.

For generic products, which are the pharmaceutical and therapeutic equivalents of branded products that are generally marketed under their generic (chemical) names rather than their brand names, our focus is on high-barrier-to-entry products, including first-to-file or first-to-market opportunities that are difficult to formulate or manufacture or face complex legal and regulatory challenges. In the U.S., a first-to-file product, also known as a Paragraph IV product, refers to a generic product for which the Abbreviated New Drug Application (ANDA) containing a patent challenge to the corresponding branded product was the first to be filed with the FDA. A first-to-market product refers to a product that is the first marketed generic equivalent of a branded product for reasons apart from statutory marketing exclusivity, such as the generic equivalent of a branded product that is difficult to formulate or manufacture. First-to-file products in the U.S. offer the opportunity for 180 days of generic marketing exclusivity, except for competing authorized generic products, to the extent we are successful in litigating any patent challenges and receive final FDA approval of the products. First-to-market products allow us to mitigate risks from competitive pressure commonly associated with commoditized generic products. Additional information is included throughout this Directors' Report.

The four reportable business segments in which we operate are: (1) U.S. Branded - Specialty & Established Pharmaceuticals, (2) U.S. Branded - Sterile Injectables, (3) U.S. Generic Pharmaceuticals and (4) International Pharmaceuticals. Additional information about our reportable business segments is included throughout this Directors' Report. The results of operations of our reportable business segments for each of the years ended December 31, 2018 and 2017 are discussed in Results of Operations within this Directors' Report.

U.S. Branded - Specialty & Established Pharmaceuticals

Our U.S. Branded - Specialty & Established Pharmaceuticals segment, which accounted for approximately 29% and 28% of total turnover in 2018 and 2017, respectively, includes a variety of branded prescription products to treat and manage conditions in urology, urologic oncology, endocrinology, pain and orthopedics. The products in this segment include XIAFLEX®, SUPPRELIN® LA, NASCOBAL® Nasal Spray, TESTOPEL®, AVEED®, PERCOCET®, VOLTAREN® Gel, LIDODERM®, FORTESTA® Gel, EDEX® and TESTIM®, among others.

U.S. Branded - Sterile Injectables

Our U.S. Branded - Sterile Injectables segment, which accounted for approximately 32% and 22% of total turnover in 2018 and 2017, respectively, consists primarily of branded sterile injectable products such as VASOSTRICT®, ADRENALIN® and APLISOL®, among others, and certain generic sterile injectable products, including ertapenem for injection and ephedrine sulfate injection, among others. These injectable products are manufactured in a sterile facility and are primarily sold through wholesalers, often via an arrangement with a group purchasing organization (GPO), in vial dosages prior to being administered at hospitals, clinics and long-term care facilities.

Our primary U.S. Branded - Sterile Injectables manufacturing site, which handles the production, assembly, quality assurance testing and packaging of our products, is located in Rochester, Michigan.

U.S. Generic Pharmaceuticals

Our U.S. Generic Pharmaceuticals segment, which accounted for approximately 34% and 44% of total turnover in 2018 and 2017, respectively, consists of a differentiated product portfolio including solid oral extended-release, solid oral immediate-release, liquids, semi-solids, patches, powders, ophthalmics and sprays and includes products in the pain management, urology, central nervous system disorders, immunosuppression, oncology, women's health and cardiovascular disease markets, among others. Our U.S. Generic Pharmaceuticals segment is among the largest U.S. generics companies based on market share. Our largest U.S. Generic Pharmaceuticals manufacturing sites, which handle the production, assembly, quality assurance testing and packaging of our generic products, are located in Chestnut Ridge, New York; Irvine, California and Chennai, India.

International Pharmaceuticals

The International Pharmaceuticals segment, which accounted for approximately 5% and 7% of total turnover in 2018 and 2017, respectively, includes a variety of specialty pharmaceutical products sold outside the U.S., primarily in Canada through our operating company Paladin Labs Inc. (Paladin). This segment's key products serve growing therapeutic areas, including attention deficit hyperactivity disorder, pain, women's health and oncology.

This segment also included: (i) our South African business, which was sold in July 2017 and consisted of Litha Healthcare Group Limited and certain assets acquired from Aspen Holdings in October 2015 (Litha) and (ii) our Latin American business consisting of Grupo Farmacéutico Somar, S.A.P.I. de C.V. (Somar), which was sold in October 2017.

Products Overview

U.S. Branded - Specialty & Established Pharmaceuticals

The following table displays the product turnover to external customers in our U.S. Branded - Specialty & Established Pharmaceuticals segment for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Specialty Products:		
XIAFLEX®	$ 264,638	$ 213,378
SUPPRELIN® LA	81,707	86,211
Other Specialty (1)	156,607	153,384
Total Specialty Products	$ 502,952	$ 452,973
Established Products:		
PERCOCET®	$ 122,901	$ 125,231
VOLTAREN® Gel	57,700	68,780
OPANA® ER	—	83,826
Other Established (2)	179,279	226,715
Total Established Products	$ 359,880	$ 504,552
Total U.S. Branded - Specialty & Established Pharmaceuticals	$ 862,832	$ 957,525

(1) Products included within Other Specialty include NASCOBAL® Nasal Spray, TESTOPEL® and AVEED®.
(2) Products included within Other Established include, but are not limited to, LIDODERM®, FORTESTA® Gel, EDEX® and TESTIM® including the authorized generics of TESTIM® and FORTESTA® Gel.

Specialty Products Portfolio

Endo commercializes a number of products within the market served by specialty distributors and specialty pharmacies, and in which healthcare practitioners can purchase and bill payers directly (the buy and bill market). Our current offerings primarily relate to two distinct areas: (i) urology treatments, which focus mainly on Peyronie's disease (PD) and testosterone replacement therapies (TRT) for hypogonadism; and (ii) orthopedics/pediatric endocrinology treatments, which focus on Dupuytren's contracture (DC) and central precocious puberty (CPP).

Key product offerings in this category include the following:

- XIAFLEX®, which is indicated for the treatment of adult patients with DC with an abnormal buildup of collagen in the fingers which limits or disables hand function. It is also indicated for the treatment of adult men with PD with a collagen plaque and a penile curvature deformity of thirty degrees or greater at the start of therapy. XIAFLEX® is the first and only FDA-approved non-surgical treatment for PD.
- SUPPRELIN® LA, which is a soft, flexible 12-month hydrogel implant based on our hydrogel polymer technology that delivers histrelin acetate, a gonadotropin releasing hormone (GnRH) agonist and is indicated for the treatment of CPP in children.
- NASCOBAL® Nasal Spray, which is a prescription medicine used as a supplement to treat vitamin B12 deficiency and is the only FDA-approved B12 nasal spray.
- TESTOPEL®, which is a unique, long-acting implantable pellet indicated for TRT in conditions associated with a deficiency or absence of endogenous testosterone.
- AVEED®, which is a novel, long-acting testosterone undecanoate for injection for the treatment of hypogonadism. AVEED® is dosed only five times per year after the first month of therapy.

Established Products Portfolio

Endo's Established Products portfolio's current treatment offerings primarily relate to two distinct areas: (i) pain management, including products in the opioid analgesics and osteoarthritis pain segments and for the treatment of pain associated with post-herpetic neuralgia; and (ii) urology, which focuses mainly on treatment of hypogonadism. The Group's legacy pain portfolio products are managed as mature brands.

Key product offerings in this category include, among others, the following:

- PERCOCET®, which is an opioid analgesic approved for the treatment of moderate-to-moderately-severe pain.
- VOLTAREN® Gel, which is a topical prescription treatment for the relief of joint pain of osteoarthritis in the knees, ankles, feet, elbows, wrists and hands. VOLTAREN® Gel delivers effective pain relief with a favorable safety profile.
- LIDODERM®, which is a topical patch product containing lidocaine, approved for the relief of pain associated with post-herpetic neuralgia, a condition thought to result after nerve fibers are damaged during a case of Herpes Zoster (commonly known as shingles).
- FORTESTA® Gel (and its authorized generic), which is a patented two percent (2%) testosterone transdermal gel and is a treatment for men suffering from hypogonadism.
- EDEX®, which is a penile injection used to treat erectile dysfunction caused by conditions affecting nerves, blood vessels, emotions and/or a combination of factors.
- TESTIM® (and its authorized generic), which is a topical gel indicated for TRT in conditions associated with a deficiency or absence of endogenous testosterone.

Also included within this product portfolio is OPANA® ER, an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. As further discussed in Results of Operations within this Directors' Report, we voluntarily ceased shipments of OPANA® ER to customers by September 1, 2017.

U.S. Branded - Sterile Injectables

The following table displays the product turnover to external customers in our U.S. Branded - Sterile Injectables segment for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
VASOSTRICT®	$ 453,767	$ 399,909
ADRENALIN®	143,489	76,523
Ertapenem for injection	57,668	—
Other Sterile Injectables (1)	274,642	274,039
Total U.S. Branded - Sterile Injectables (2)	$ 929,566	$ 750,471

(1) Products included within Other Sterile Injectables include, but are not limited to, APLISOL® and ephedrine sulfate injection.

(2) Individual products presented above represent the top two performing products for this segment and/or any product having turnover in excess of $100 million during any of the years ended December 31, 2018 and 2017 or $25 million during any quarterly period in 2018.

The U.S. Branded - Sterile Injectables segment includes a product portfolio of approximately 30 product families, including branded sterile injectable products that are protected by certain patent rights and have inherent scientific, regulatory, legal and technical complexities and generic injectable products that are difficult to formulate or manufacture or face complex legal and regulatory challenges. Sterile injectables in this segment are manufactured in a sterile facility and are sold primarily in vial dosages and administered at hospitals, clinics and long-term care facilities. The product offerings in this segment include, among others, the following:

- VASOSTRICT®, which is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines. VASOSTRICT® is currently the first and only vasopressin injection with an NDA approved by the FDA. As of December 31, 2018, we have six patents for VASOSTRICT® listed in the Orange Book. We have additional patents pending with the PTO. The FDA requires any applicant (as further described below under the heading "Governmental Regulation") seeking FDA approval for vasopressin prior to patent expiry and relying on VASOSTRICT® as the Reference Listed Drug to notify us of its filing before the FDA will issue an approval.
- ADRENALIN®, which is a non-selective alpha and beta adrenergic agonist indicated for emergency treatment of certain allergic reactions, including anaphylaxis.
- Ertapenem for injection, the authorized generic of Merck Sharp & Dohme Corp's Invanz®, which is indicated for the treatment of certain moderate-to-severe infections.
- APLISOL®, which is a sterile aqueous solution of a purified protein derivative for intradermal administration as an aid in the diagnosis of tuberculosis.
- Ephedrine sulfate injection, which is an alpha and beta adrenergic agonist and a norepinephrine-releasing agent indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

U.S. Generic Pharmaceuticals

The U.S. Generic Pharmaceuticals segment includes a product portfolio of over 200 generic prescription product families including solid oral extended-release, solid oral immediate-release, liquids, semi-solids, patches (which are medicated adhesive patches designed to deliver the drug through the skin), powders, ophthalmics (which are sterile pharmaceutical preparations administered for ocular conditions) and sprays and includes products in the pain management, urology, central nervous system disorders, immunosuppression, oncology, women's health and cardiovascular disease markets, among others.

Generic drugs are the pharmaceutical and therapeutic equivalents of branded products and are generally marketed under their generic (chemical) names rather than by brand names. Generic products are substantially the same as branded products in dosage form, safety, efficacy, route of administration, quality, performance characteristics and intended use, but are generally sold at prices below those of the corresponding branded products and thus represent cost-effective alternatives for consumers.

Typically, a generic drug may not be marketed until the expiration of applicable patent(s) on the corresponding branded product unless a resolution of patent litigation results in an earlier opportunity to enter the market. However, our generics portfolio also contains certain authorized generics, which are generic versions of branded drugs licensed by brand drug companies under an NDA and marketed as generics. Authorized generics do not face regulatory barriers to introduction and are not prohibited from sale during the 180-day marketing exclusivity period granted to the first-to-file ANDA applicant. Our authorized generics include lidocaine patch 5% (LIDODERM®), budesonide (Entocort® EC), and diclofenac sodium gel (VOLTAREN® Gel), among others. We believe we are a partner of choice to larger brand companies seeking an authorized generics distributor for their branded products. We have been the authorized generic distributor for such companies as AstraZeneca plc, Bristol-Myers Squibb Company, Novartis AG (Novartis) and Merck Sharp & Dohme Corp.

International Pharmaceuticals

Our International Pharmaceuticals segment includes a variety of specialty pharmaceutical products sold outside the U.S., primarily in Canada through our operating company Paladin. This segment's key products serve growing therapeutic areas, including attention deficit hyperactivity disorder, pain, women's health and oncology.

Select Products in Development

Collagenase Clostridium Histolyticum

Collagenase clostridium histolyticum (CCH) is currently approved and marketed in the U.S. under the trademark XIAFLEX® for the treatment of both DC and PD (two separate medical indications).

We are currently progressing the cellulite treatment development program for CCH. In November 2018, we reported positive results from two Phase 3 clinical trials of CCH for the treatment of cellulite in the buttocks. Trial subjects receiving CCH showed highly statistically significant levels of improvement in the appearance of cellulite with treatment, as measured by the trials' primary endpoint. In addition, the RELEASE-1 trial passed 8 out of 8 key secondary endpoints and the RELEASE-2 trial passed 7 out of 8 key secondary endpoints. Finally, CCH was well-tolerated in the actively-treated subjects with most adverse events being mild to moderate in severity and primarily limited to the local injection area.

We have global marketing rights for CCH for the treatment of cellulite. We also have the right to further develop CCH for additional indications, including Dupuytren's nodules, adhesive capsulitis, lateral hip fat, plantar fibromatosis and human and canine lipomas on the medical therapeutic side, as well as other potential aesthetic indications.

Other Pharmaceutical Pipeline

Our remaining pipeline consists mainly of a variety of pharmaceutical products in our U.S. Generic Pharmaceuticals and U.S. Branded - Sterile Injectables segments. Our primary approach to developing generic products, including injectables, is to target high-barrier-to-entry generic product opportunities, including first-to-file or first-to-market opportunities that are difficult to formulate or manufacture or face complex legal and regulatory challenges. We expect such product opportunities to result in products that are either the exclusive generic or have two or fewer generic competitors when launched, which we believe tends to lead to more sustainable market share and profitability for our product portfolio. In our U.S. Branded - Sterile Injectables business, we also focus on developing branded injectable products with inherent scientific, regulatory, legal and technical complexities and developing other dosage forms and technologies.

As of December 31, 2018, these two segments had over 150 product candidates in their pipelines, which included approximately 85 ANDAs pending with the FDA representing approximately $25 billion of combined annual sales for the corresponding branded products in 2018. Of the 85 ANDAs, approximately 40 represent first-to-file opportunities or first-to-market opportunities. These numbers do not include the five sterile injectable product candidates licensed during the second quarter of 2018 from Nevakar, Inc.

We periodically review our development projects in order to better direct investment toward those opportunities that we expect will deliver the greatest returns. This process can lead to decisions to discontinue certain R&D projects that may reduce the number of products in our previously reported pipeline.

Competition

Branded Pharmaceuticals

Our branded pharmaceutical products compete with products manufactured by many other companies in highly competitive markets throughout the U.S. and internationally, primarily through Paladin.

We compete principally through targeted product development and our acquisition and in-licensing strategies. The competitive landscape in the acquisition and in-licensing of pharmaceutical products has intensified in recent years as a result of a reduction in the number of compounds available and an increase in competitors bidding on available assets. In addition to product development and acquisitions, other competitive factors in the pharmaceutical industry include product efficacy, safety, ease of use, price, demonstrated cost-effectiveness, marketing effectiveness, service, reputation and access to technical information.

Certain of the new products that we introduce must compete with other products already on the market or products that are later developed by competitors, including both competing brands and generic equivalents. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions and/or decreased volume of sales. Accordingly, the competitive environment of the branded product business requires us to continually seek out technological innovations and to market our products effectively. To successfully compete for business of managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits but also cost advantages as compared with other forms of care.

Manufacturers of generic pharmaceuticals typically invest far less in R&D than research-based pharmaceutical companies and therefore can price their products significantly lower than branded products. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. Due to their significantly lower prices, generic versions, where available, may be substituted by pharmacies or required in preference to the branded version under third-party reimbursement programs.

U.S. Branded - Specialty & Established Pharmaceuticals

This segment's major competitors, including Mylan N.V. (Mylan), Allergan plc (Allergan), Purdue Pharma, L.P. (Purdue), Jazz Pharmaceuticals plc (Jazz), Takeda Pharmaceutical Company Limited (Takeda), Horizon Pharma plc (Horizon) and Mallinckrodt plc (Mallinckrodt), among others, vary depending on therapeutic and product category, dosage strength and drug-delivery systems.

Several of this segment's products, including, for example, PERCOCET®, VOLTAREN® Gel, LIDODERM® and TESTIM®, face generic competition. In addition, we are aware of certain competitive activities involving certain of our branded products. For a description of material competitive activities, including litigation related to Paragraph IV notices, see Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report.

U.S. Branded - Sterile Injectables

This segment's major competitors, including Hospira, Inc. (a subsidiary of Pfizer Inc.), Fresenius Kabi, Mylan and Hikma Pharmaceuticals PLC, vary by product. A significant portion of our sales, including sales to over 5,500 hospitals, clinics and long-term care facilities in the U.S., are controlled by a relatively small number of GPOs, including HealthTrust Purchasing Group LP, Premier Inc. and Vizient Inc. Accordingly, it is important for us to have strong relationships with these GPOs and achieve on-time product launches in order to secure new bid opportunities.

Of the approximately 30 product families in our sterile injectables portfolio, 15 have fewer than two competitors and 17 have fewer than three competitors. Additional competitors increase the degree of price competition from generic forms of our products.

Generic Pharmaceuticals

In the generic pharmaceutical market, we face intense competition from other generic drug manufacturers, brand name pharmaceutical companies through authorized generics, existing brand equivalents and manufacturers of therapeutically similar drugs. Our major competitors in the generics market, including Teva Pharmaceutical Industries Limited (Teva), Mylan, Sandoz (a division of Novartis AG) and Amneal Pharmaceuticals, Inc. (Amneal) vary by product.

A significant portion of our sales are made through a relatively small number of drug wholesalers and retail drug store chains. These customers play a key role in the distribution chain of our pharmaceutical products. Drug wholesalers and retail drug store chains have undergone, and are continuing to undergo, significant consolidation, which has resulted in these groups gaining additional purchasing leverage that has increased the pricing pressures on our business. Additionally, the emergence of large buying groups representing independent retail pharmacies and other drug distributors, and the prevalence and influence of managed care organizations and similar institutions increases the negotiating power of these groups, potentially enabling them to attempt to extract price discounts, rebates and other restrictive pricing terms on our products. For example, McKesson Corporation and Wal-Mart Stores, Inc. are party to an agreement to jointly source generic pharmaceuticals and Express Scripts, through a wholly owned subsidiary, Innovative Product Alignment, LLC, announced it will participate in the Walgreens Boots Alliance Development GmbH group purchasing organization. As a result of these alliances, the consolidation among wholesale distributors and the growth of large retail drug store chains, a small number of purchasers control a significant share of purchases and have gained more purchasing power that has heightened competition among generic drug producers for the business of this consolidated customer base.

Newly introduced generic products with limited or no other generic competition typically garner higher prices relative to commoditized generic products. As such, our primary strategy is to compete in the generic product market with a focus on high-value, first-to-file or first-to-market opportunities, regardless of therapeutic category, and products that present significant barriers to entry for reasons such as complex formulation or regulatory or legal challenges.

At the expiration of any statutory generic exclusivity period, other competitors may enter the market, resulting in significant price declines. Consequently, maintaining profitable operations in generic pharmaceuticals depends, in part, on our continuing ability to select, develop, procure regulatory approvals of, overcome legal challenges to, launch and commercialize new generic products in a timely and cost efficient manner and to maintain efficient, high quality manufacturing capabilities.

Seasonality

Although our business is affected by the purchasing patterns and concentration of our customers, our business is not materially impacted by seasonality.

Major Customers

We primarily sell our generic and branded pharmaceuticals to wholesalers, retail drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, hospitals and government agencies. Our wholesalers and distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies and managed health care organizations. Customers in the managed health care market include health maintenance organizations, nursing homes, hospitals, clinics, pharmacy benefit management companies and mail order customers. Total turnover from direct customers that accounted for 10% or more of our total consolidated turnover during the years ended December 31, 2018 and 2017 are as follows:

	2018	2017
AmerisourceBergen Corporation	32%	25%
McKesson Corporation	27%	25%
Cardinal Health, Inc.	26%	25%

Turnover from these customers are included within each of our segments.

As a result of consolidation among wholesale distributors and the growth of large retail drug store chains, a small number of large wholesale distributors control a significant share of the market, and the number of independent retail drug stores and small retail drug store chains has decreased. Some wholesale distributors have demanded that pharmaceutical manufacturers, including us, enter into distribution service agreements (DSAs) pursuant to which the wholesale distributors provide the pharmaceutical manufacturers with specific services, including the provision of periodic retail demand information and current stock levels and other information. We have entered into certain of these agreements.

Patents, Trademarks, Licenses and Proprietary Property

As of February 21, 2019, we held approximately: 225 U.S. issued patents, 50 U.S. patent applications pending, 476 foreign issued patents and 94 foreign patent applications pending. In addition, as of February 21, 2019, we have licenses for approximately 46 U.S. issued patents, 8 U.S. patent applications pending, 172 foreign issued patents and 64 foreign patent applications pending. The following table sets forth information as of February 21, 2019 regarding patents relating to each of our most significant products:

Patent No.	Patent Expiration*	Relevant Product	Ownership	Jurisdiction Where Granted
7,718,640	March 14, 2027	AVEED®	Exclusive License	United States
8,338,395	February 27, 2026	AVEED®	Exclusive License	United States
RE39,941	August 24, 2019	XIAFLEX®	Exclusive License	United States
6,022,539	June 3, 2019	XIAFLEX®	Exclusive License	United States
7,811,560	July 12, 2028	XIAFLEX®	Owned; Exclusive License	United States
7,229,636	August 1, 2024	NASCOBAL® Nasal Spray	Owned	United States
7,404,489	March 12, 2024	NASCOBAL® Nasal Spray	Owned	United States
7,879,349	August 1, 2024	NASCOBAL® Nasal Spray	Owned	United States
8,003,353	August 1, 2024	NASCOBAL® Nasal Spray	Owned	United States
8,940,714	February 26, 2024	NASCOBAL® Nasal Spray	Owned	United States
9,415,007	July 28, 2024	NASCOBAL® Nasal Spray	Owned	United States
9,375,478	January 30, 2035	VASOSTRICT®	Owned	United States
9,687,526	January 30, 2035	VASOSTRICT®	Owned	United States
9,744,209	January 30, 2035	VASOSTRICT®	Owned	United States
9,744,239	January 30, 2035	VASOSTRICT®	Owned	United States
9,750,785	January 30, 2035	VASOSTRICT®	Owned	United States
9,937,223	January 30, 2035	VASOSTRICT®	Owned	United States
9,119,876	March 13, 2035	ADRENALIN®	Owned	United States
9,295,657	March 13, 2035	ADRENALIN®	Owned	United States

* Our license agreements for the patents in the table above extend to or beyond the patent expiration dates.

The effect of these issued patents is that they provide us with protection by virtue of our ability to exclude others from making, using, selling, offering for sale and importing that which is covered by their claims. The coverage claimed in a patent application can be significantly reduced before the patent is issued. Accordingly, we do not know whether any of the applications we acquire or license will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications are maintained in secrecy for a period of eighteen months and U.S. patent applications filed prior to November 29, 2000 are not disclosed until such patents are issued, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference and other inter-parties proceedings declared by the PTO to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that any patents, if issued, will be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes, trade secrets, know-how, innovations and all of our intellectual property are important to our business and achieving a competitive position. Many of our products are sold under trademarks. To achieve a competitive position, we rely on trade secrets, non-patented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable. In addition, as outlined above, we have a number of patent licenses from third parties, some of which may be important to our business. See Note 10. License and Collaboration Agreements of the accompanying Consolidated Financial Statements included in this report. There can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition.

We rely on confidentiality agreements with our employees, consultants and other parties to protect, among other things, trade secrets and other proprietary technology. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that other third parties will not otherwise gain access to our trade secrets and other intellectual property.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our intellectual property or trade secrets or to determine the scope and validity of the proprietary rights of others. Litigation is costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that we will prevail in any such litigation. See Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report.

Service Agreements

We contract with various third parties to provide certain critical services including manufacturing, supply, warehousing, distribution, customer service, certain financial functions, certain research and development activities and medical affairs.

For a description of our significant manufacturing, supply and other service agreements, see Note 10. License and Collaboration Agreements and Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report.

We primarily purchase our raw materials for the production and development of our products in the open market from third party suppliers. However, some raw materials are only available from one source. We attempt, when possible, to mitigate our raw material supply risks through stock management and alternative sourcing strategies. We are required to identify the suppliers of all raw materials for our products in the drug applications that we file with the FDA. If the raw materials from an approved supplier for a particular product become unavailable, we would be required to qualify a substitute supplier with the FDA, which would likely interrupt manufacturing of the affected product. See "Principal Risks" for further discussion on the risks associated with the sourcing of our raw materials.

License and Collaboration Agreements and Acquisitions

We continue to seek to enhance our product line and develop a balanced portfolio of differentiated products through product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties. The Group enters into strategic alliances and collaborative arrangements with third parties, which give the Group rights to develop, manufacture, market and/or sell pharmaceutical products, the rights to which are primarily owned by these third parties. These alliances and arrangements can take many forms, including licensing arrangements, co-development and co-marketing agreements, co-promotion arrangements, research collaborations and joint ventures. Such alliances and arrangements enable us to share the risk of incurring all research and development expenses that do not lead to turnover-generating products; however, because profits from alliance products are shared with the counter-parties to the collaborative arrangement, the gross margins on alliance products are generally lower, sometimes substantially so, than the gross margins that could be achieved had the Group not opted for a development partner.

Environmental Matters

Our operations are subject to substantial federal, state and local environmental laws and regulations concerning, among other matters, the generation, handling, storage, transportation, treatment and disposal of, and exposure to, hazardous substances. Violation of these laws and regulations, which may change, can lead to substantial fines and penalties. Many of our operations require environmental permits and controls to prevent and limit pollution of the environment. We believe that our facilities and the facilities of our third party service providers are in substantial compliance with applicable environmental laws and regulations and we do not believe that future compliance will have a material adverse effect on our financial condition or results of operations.

Employees

As of February 21, 2019, we have 2,910 employees, of which 432 are engaged in research and development and regulatory work, 390 in sales and marketing, 1,070 in manufacturing, 557 in quality assurance and 461 in general and administrative capacities. Our employees are generally not represented by unions, with the exception of certain production personnel in our Rochester, Michigan manufacturing facility. We believe that our relations with our employees are good.

Review of the Performance of the Business

Overview

This executive summary provides 2018 highlights from the results of operations that follow:

- Total turnover in 2018 decreased 15% to $2,947.1 million compared to $3,468.9 million in 2017 as strong performance from our U.S. Branded - Sterile Injectables segment and our U.S. Branded - Specialty & Established Pharmaceuticals segment's Specialty Products portfolio was more than offset by declines in our U.S. Branded - Specialty & Established Pharmaceuticals segment's Established Products portfolio, including a decrease of $83.8 million resulting from the voluntary withdrawal of OPANA® ER that is further described below, our U.S. Generic Pharmaceuticals segment and, following our 2017 divestitures of Litha and Somar that are further described below, our International Pharmaceuticals segment.
- Gross margin percentage in 2018 increased to 44.6% from 35.8% in 2017, reflecting a shift in product mix to higher margin products, the impact of product rationalization and operating efficiency efforts and decreased intangible asset amortization expense.
- Asset impairment charges in 2018 decreased to $916.9 million from $1,154.4 million in 2017.
- During 2018, we recognized income tax expense of $22.9 million on $938.8 million of loss from continuing operations before income tax, compared to tax benefit of $250.3 million on $1,483.0 million of loss from continuing operations before income tax during 2017. This change reflects differences in the geographic mix of pre-tax earnings and the establishment of a valuation allowance against certain U.S. deferred tax assets in 2017.
- Loss from continuing operations in 2018 was $961.8 million, compared to $1,232.7 million in 2017.

Additionally, the following summary highlights certain key events that occurred during 2018:

- In January 2018, the Group initiated a restructuring initiative that included a reorganization of its U.S. Generic Pharmaceuticals segment's research and development network, a further simplification of the Group's manufacturing networks and a group-wide unification of certain corporate functions.
- During the second quarter of 2018, we entered into a development, license and commercialization agreement with Nevakar, Inc. related to five sterile injectable product candidates.
- In November 2018, we reported positive results from two Phase 3 clinical trials of CCH for the treatment of cellulite in the buttocks. Trial subjects receiving CCH showed highly statistically significant levels of improvement in the appearance of cellulite with treatment, as measured by the trials' primary endpoint. In addition, the RELEASE-1 trial passed 8 out of 8 key secondary endpoints and the RELEASE-2 trial passed 7 out of 8 key secondary endpoints. Finally, CCH was well-tolerated in the actively-treated subjects with most adverse events being mild to moderate in severity and primarily limited to the local injection area.

Strategy

Our strategy is to focus on our core assets, a branded pharmaceutical business and a leading generics business, that deliver high quality medicines to patients through excellence in development, manufacturing and commercialization. Through a lean and efficient operating model, we are committed to serving patients and customers while continuing to innovate and provide products that make a difference in the lives of patients. We strive to maximize shareholder value by adapting to market realities and customer needs.

We are committed to driving organic growth at attractive margins by improving execution, optimizing cash flow and leveraging our market position, while maintaining a streamlined cost structure throughout each of our businesses. Specific areas of management's focus include:

- U.S. Branded - Specialty & Established Pharmaceuticals: Accelerating performance of organic growth drivers in our Specialty Products portfolio, expanding margin in our Established Products portfolio and investing in key pipeline development opportunities, including in the area of aesthetics.
- U.S. Branded - Sterile Injectables: Focusing on developing branded injectable products with inherent scientific, regulatory, legal and technical complexities, expanding the product portfolio to include other dosages and technologies and/or acquiring additional high-barrier-to-entry, generic injectable products that are difficult to manufacture.
- U.S. Generic Pharmaceuticals: Focusing on developing or acquiring high-barrier-to-entry products, including first-to-file or first-to-market opportunities that are difficult to formulate or manufacture or face complex legal and regulatory challenges.
- International Pharmaceuticals: Operating in regulated markets with durable turnover streams and where physicians play a significant role in choosing the course of therapy, as well as expanding distribution of certain of our existing products outside of the U.S.

We will continue to evaluate strategic R&D opportunities. Going forward, while our primary focus will be on organic growth, we will evaluate and, where appropriate, execute on opportunities to expand through acquisitions of products and companies.

Results of Operations

Consolidated Results Review

The following table displays our turnover, gross margin, gross margin percentage and other pre-tax expense or profit for the years ended December 31, 2018 and 2017 (dollars in thousands):

			% Change
	2018	2017	2018 vs. 2017
Total turnover	$ 2,947,078	$ 3,468,858	(15)%
Cost of sales	1,631,682	2,228,530	(27)%
Gross margin	$ 1,315,396	$ 1,240,328	6 %
Gross margin percentage	*44.6%*	*35.8%*	
Selling, general and administrative	646,037	629,874	3 %
Research and development	185,826	172,067	8 %
Litigation-related and other contingencies, net	13,809	185,990	(93)%
Asset impairment charges	916,939	1,154,376	(21)%
Acquisition-related and integration items	21,914	58,086	(62)%
Interest expense, net	521,656	488,228	7 %
Loss on extinguishment of debt	—	51,734	(100)%
Other income, net	(51,953)	(17,023)	NM
Loss from continuing operations before income tax	$ (938,832)	$ (1,483,004)	(37)%

NM indicates that the percentage change is not meaningful or is greater than 100%.

Total turnover. In 2018, total turnover decreased primarily due to the impact of the second quarter 2017 loss of marketing exclusivity for both ezetimibe tablets and quetiapine ER tablets, competitive pressure on commoditized generic products, generic product rationalization initiatives, actions taken with respect to the voluntary withdrawal of OPANA® ER that are further described below, generic competition on our U.S. Branded - Specialty & Established Pharmaceuticals segment's Established Products portfolio, our divestitures of Litha and Somar in the second half of 2017. These declines were partially offset by continued strong performance from our U.S. Branded - Sterile Injectables segment, including increases in turnover from VASOSTRICT®, ADRENALIN® and from our third quarter 2018 launch of ertapenem for injection, the authorized generic of Invanz®, our U.S. Branded - Specialty & Established Pharmaceuticals segment's Specialty Products portfolio, which includes XIAFLEX®, and the impact of certain other recent product launches including, among others, colchicine tablets, the authorized generic of Takeda Pharmaceuticals U.S.A., Inc.'s Colcrys®, which launched in July 2018.

In March 2017, we announced that the FDA's Drug Safety and Risk Management and Anesthetic and Analgesic Drug Products Advisory Committees voted that the benefits of reformulated OPANA® ER (oxymorphone hydrochloride extended release) no longer outweigh its risks. In June 2017, we became aware of the FDA's request that we voluntarily withdraw OPANA® ER from the market and, in July 2017, after careful consideration and consultation with the FDA, we decided to voluntarily remove OPANA® ER from the market. During the second quarter of 2017, we began to work with the FDA to coordinate an orderly withdrawal of the product from the market. By September 1, 2017, we ceased shipments of OPANA® ER to customers and we expect the NDA will be withdrawn. These actions had an adverse effect on the turnover and results of operations of our U.S. Branded - Specialty & Established Pharmaceuticals segment in 2017 and 2018.

Cost of sales and gross margin percentage. During the years ended December 31, 2018 and 2017, we incurred certain charges that impact the comparability of total Cost of sales, including, among others, those related to acquisitions, separation benefits and restructuring initiatives. The following table summarizes such amounts (in thousands):

	2018	2017
Amortization of intangible assets (1)	$ 622,339	$ 773,766
Stock step-up and certain manufacturing costs that will be eliminated pursuant to integration plans	$ 261	$ 390
Separation benefits and other cost reduction initiatives (2)	$ 60,434	$ 175,809

(1) Amortization expense fluctuates based on changes in the total amount of amortizable intangible assets and the rate of amortization in effect for each intangible asset, both of which can vary based on factors such as the amount and timing of acquisitions, dispositions, asset impairment charges, transfers between indefinite- and finite-lived intangibles assets, changes in foreign currency rates and changes in the composition of our intangible assets impacting the weighted average useful lives and amortization methodologies being utilized. The decrease in 2018 was primarily driven by the impact of 2017 amortization expense for both ezetimibe tablets and quetiapine ER tablets, which were fully amortized prior to January 1, 2018, the impact of asset impairment charges and decreases in the rate of amortization expense for certain assets, partially offset by the impact of certain in-process research and development assets put into service.

(2) Amounts primarily relate to certain employee separation costs, accelerated depreciation charges, charges to increase excess stock reserves related to restructurings and other cost reduction and restructuring charges. See Note 4. Restructuring of the accompanying Consolidated Financial Statements included in this report for discussion of our material restructuring initiatives.

The previously described decrease in total turnover, the decrease to amortization expense and decreased restructuring charges were the primary factors leading to the overall period-over-period decrease in Cost of sales in 2018.

The increase in gross margin percentage in 2018 was primarily attributable to the gross margin effects of the net Cost of sales decreases included in the table above, the favorable margin impact of product rationalization and operating efficiency efforts and changes in the mix of total turnover, including a shift from generic to branded products.

Our material restructuring initiatives are described more fully in Note 4. Restructuring of the accompanying Consolidated Financial Statements included in this report.

Selling, general and administrative expenses. In 2018, Selling, general and administrative expenses increased primarily as a result of increased legal costs related to certain litigation matters, partially offset by cost reductions that were implemented throughout 2017 and 2018, including the impact of those related to various restructuring initiatives.

Our material restructuring initiatives and material legal proceedings and other contingent matters are described in more detail in Note 4. Restructuring and Note 13. Commitments and Contingencies, respectively, of the accompanying Consolidated Financial Statements included in this report.

Research and development expenses. Our R&D efforts are focused on the development of a balanced, diversified portfolio of innovative and clinically differentiated product candidates, including CCH for the treatment of cellulite. We also seek out and develop high-barrier-to-entry generic products, including first-to-file or first-to-market opportunities. We periodically review our generic products pipeline in order to better direct investment toward those opportunities that we expect will deliver the greatest returns.

In November 2018, we reported positive results from two Phase 3 clinical trials, which had been initiated during the first quarter of 2018, of CCH for the treatment of cellulite in the buttocks. Trial subjects receiving CCH showed highly statistically significant levels of improvement in the appearance of cellulite with treatment, as measured by the trials' primary endpoint. In addition, the RELEASE-1 trial passed 8 out of 8 key secondary endpoints and the RELEASE-2 trial passed 7 out of 8 key secondary endpoints. Finally, CCH was well-tolerated in the actively-treated subjects with most adverse events being mild to moderate in severity and primarily limited to the local injection area.

During the second quarter of 2018, we entered into a development, license and commercialization agreement related to five sterile injectable product candidates, at which time we became obligated to make an upfront payment, which was recorded as Research and development expense in the Consolidated Profit and Loss Account. This agreement is described more fully in Note 10. License and Collaboration Agreements of the accompanying Consolidated Financial Statements included in this report.

Also, during the first quarter of 2018, we announced the January 2018 Restructuring Initiative, which included a reorganization of our U.S. Generic Pharmaceuticals segment's research and development network.

The increase in R&D expense in 2018 was primarily a result of increased costs related to our cellulite treatment development program and the upfront payment discussed above. This increase was partially offset by cost savings related to the January 2018 Restructuring Initiative and other cost reduction initiatives.

We expect our U.S. Branded - Specialty & Established Pharmaceuticals segment's R&D costs to decline in 2019. This expected decline primarily reflects lower R&D expenditures related to CCH for the treatment of cellulite as a result of the timing of our Phase 3 trials, the results of which were announced in November 2018. However, there can be no assurance that we will achieve these results.

Our material restructuring initiatives are described more fully in Note 4. Restructuring of the accompanying Consolidated Financial Statements included in this report.

Litigation-related and other contingencies, net. Included within Litigation-related and other contingencies, net are changes to our accruals for litigation-related settlement charges and certain settlements proceeds related to suits filed by our subsidiaries. Our material legal proceedings and other contingent matters are described in more detail in Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report.

Asset impairment charges. The following table presents the components of our total Asset impairment charges for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Goodwill impairment charges	$ 680,000	$ 288,745
Other intangible asset impairment charges	230,418	799,955
Tangible fixed asset impairment charges	6,521	65,676
Total asset impairment charges	$ 916,939	$ 1,154,376

The factors leading to our material asset impairment tests, as well as the results of these tests, are further described in Note 8. Tangible Fixed Assets and Note 9. Goodwill and Other Intangibles of the accompanying Consolidated Financial Statements included in this report.

Acquisition-related and integration items. The following table presents the components of our total Acquisition-related and integration items for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Net expense from changes in the fair value of acquisition-related contingent consideration	$ 19,910	$ 49,949
Other	2,004	8,137
Acquisition-related and integration items	$ 21,914	$ 58,086

Net expense from changes in the fair value of acquisition-related contingent consideration resulted primarily from changes to our estimates regarding the timing and amount of the future turnover of the underlying products and changes in other assumptions impacting the probability of, and extent to which we will incur related contingent obligations. See Note 6. Fair Value Measurements of the accompanying Consolidated Financial Statements included in this report for further discussion of our acquisition-related contingent consideration.

The decrease in other Acquisition-related and integration items in 2018 was primarily attributable to the timing of prior acquisitions and the associated costs.

Interest expense, net. The components of Interest expense, net for the years ended December 31, 2018 and 2017 are as follows (in thousands):

	2018	2017
Interest expense	$ 534,850	$ 494,694
Interest income	(13,194)	(6,466)
Interest expense, net	$ 521,656	$ 488,228

The increase in interest expense in 2018 was primarily attributable to increased interest rates, including the effects of both increases in LIBOR, which impacted our variable-rate debt, and the refinancing that occurred on April 27, 2017, which is further described in Note 12. Debt of the accompanying Consolidated Financial Statements included in this report. Although we cannot predict future interest rates with certainty, absent any actions to reduce the principal amount of our debt, interest expense is likely to increase in 2019 as a result of recent and potential future increases in LIBOR.

Interest income varies primarily based on the amounts of our investments in money market funds and time deposits, as well as changes in the corresponding interest rates.

Loss on extinguishment of debt. Loss on extinguishment of debt in 2017 related to certain previously unamortized debt issuance costs that were charged to expense in connection with the April 2017 refinancing. There were no comparable charges in 2018.

Other income, net. The components of Other income, net for the years ended December 31, 2018 and 2017 are as follows (in thousands):

	2018	2017
Net gain on sale of business and other assets	$ (45,155)	$ (13,809)
Foreign currency gain, net	(3,762)	(2,801)
Net loss from our investments in the equity of other companies	3,444	898
Other miscellaneous, net	(6,480)	(1,311)
Other income, net	$ (51,953)	$ (17,023)

In 2018, Net gain on sale of business and other assets primarily relates to proceeds received from the 2018 sales of various ANDAs and of the Huntsville facilities, as further discussed in Note 4. Restructuring of the accompanying Consolidated Financial Statements included in this report.

In 2017, Net gain on sale of business and other assets includes a $10.1 million gain resulting from the sale of Litha, as further described in Note 3. Discontinued Operations and Divestitures of the accompanying Consolidated Financial Statements included in this report.

Amounts of Foreign currency gain, net result from the remeasurement of the Group's foreign currency denominated assets and liabilities. Net loss from our investments in the equity of other companies includes the profit and loss account impacts of our investments in the equity of other companies, including those accounted for under the equity method and those classified as marketable securities.

Income tax expense (benefit). The following table displays our Loss from continuing operations before income tax, Income tax expense (benefit) and effective tax rate for the years ended December 31, 2018 and 2017 (dollars in thousands):

	2018	2017
Loss from continuing operations before income tax	$ (938,832)	$ (1,483,004)
Income tax expense (benefit)	$ 22,935	$ (250,293)
Effective tax rate	*(2.4)%*	*16.9%*

Our tax rate is affected by recurring items, such as tax rates in non-U.S. jurisdictions as compared to the notional U.S. federal statutory tax rate, and the relative amount of profit or loss in those various jurisdictions. It is also impacted by certain items that may occur in any given period, but are not consistent from period to period.

The tax expense in 2018 primarily related to the establishment of a valuation allowance against certain U.S. deferred tax assets. The following items had the most significant impact on the difference between the notional U.S. statutory federal income tax rate and our effective tax rate in 2017:

2017:

- $1,648.8 million of tax expense or a 111.2% rate charge from recording net valuation allowances relating to the Group's operations.
- $1,350.8 million of net tax benefit or a 91.1% rate benefit associated with our geographical mix of earnings. As of December 31, 2017, no provision has been made for Irish taxes, as the majority of our undistributed earnings were considered to be permanently reinvested outside of Ireland.
- $56.1 million of net tax benefit or a 3.8% rate benefit associated with the divestiture of certain International Pharmaceuticals segment businesses.
- $60.8 million of tax expense or a 4.1% rate charge resulting from the non-deductible portion of impaired goodwill.

We have valuation allowances established against our deferred tax assets in most other jurisdictions in which we operate, with the exception of Canada and India. Accordingly, it would be unlikely for future pre-tax losses to create a tax benefit that would be more likely than not to be realized. Although the Group has valuation allowances established against deferred tax assets in most major jurisdictions as of December 31, 2018, it is possible that there could be material releases if certain proposed law changes were to be enacted.

The Internal Revenue Service (IRS) presently is examining certain of our subsidiaries' U.S. income tax returns for fiscal years ending between December 31, 2011 and December 31, 2015 and, in connection with those examinations, is reviewing our tax positions related to, among other things, certain intercompany arrangements, including the level of profit earned by our United States subsidiaries pursuant to such arrangements, and a worthless stock deduction directly attributable to product liability losses. The IRS may examine our tax returns for other fiscal years and/or for other tax positions. Similarly, other tax authorities may examine our non-U.S. tax returns and propose adjustments to our taxes. Such examinations may lead to proposed or actual adjustments to our taxes that may be material, individually or in the aggregate. An adverse outcome of these tax examinations could have a material adverse effect on our business, financial position, results of operations and growth prospects. See the principal risk "We may not be able to successfully maintain our low tax rates or other tax positions, which could adversely affect our businesses and financial condition, results of operations and growth prospects" in "Principal Risks" for more information.

For additional information on our income taxes, see Note 18. Income Taxes of the accompanying Consolidated Financial Statements included in this report.

Discontinued operations, net of tax. As further described in Note 3. Discontinued Operations and Divestitures of the accompanying Consolidated Financial Statements included in this report, the operating results of Astora are reported as Discontinued operations, net of tax in the Consolidated Profit and Loss Account for all periods presented. The results of our discontinued operations, net of tax, were losses of $69.7 million and $802.7 million, during the years ended December 31, 2018 and 2017, respectively.

In 2018, the primary driver of the change was the after-tax impact of charges related to mesh litigation. Mesh-related charges in 2018 totaled $34.0 million compared to $775.5 million in 2017. Additionally, following the settlement strategy we pursued in 2017, there were decreases in mesh-related legal defense costs in 2018 compared to 2017.

For further discussion of mesh-related matters, refer to Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report.

Business Segment Results Review

The four reportable business segments in which we operate are: (1) U.S. Branded - Specialty & Established Pharmaceuticals, (2) U.S. Branded - Sterile Injectables, (3) U.S. Generic Pharmaceuticals and (4) International Pharmaceuticals. Our segments reflect the level at which the chief operating decision maker regularly reviews financial information to assess performance and to make decisions about resources to be allocated. Each segment derives turnover from the sales or licensing of its respective products and is discussed in more detail below.

We evaluate segment performance based on each segment's adjusted profit from continuing operations before income tax, a financial measure not determined in accordance with U.S. GAAP, which we define as Loss from continuing operations before income tax and before certain upfront and milestone payments to partners; acquisition-related and integration items, including transaction costs and changes in the fair value of contingent consideration; cost reduction and integration-related initiatives such as separation benefits, retention payments, other exit costs and certain costs associated with integrating an acquired company's operations; asset impairment charges; amortization of intangible assets; stock step-up recorded as part of our acquisitions; litigation-related and other contingent matters; gains or losses from early termination of debt; gains or losses from the sales of businesses and other assets; foreign currency gains or losses on intercompany financing arrangements; and certain other items.

Certain of the corporate expenses incurred by us are not attributable to any specific segment. Accordingly, these costs are not allocated to any of our segments and are included in the results below as "Corporate unallocated costs." Interest income and expense are also considered corporate items and not allocated to any of our segments. Our consolidated adjusted profit from continuing operations before income tax is equal to the combined results of each of our segments less these unallocated corporate items.

We refer to adjusted profit from continuing operations before income tax in making operating decisions because we believe it provides meaningful supplemental information regarding our operational performance. For instance, we believe that this measure facilitates internal comparisons to our historical operating results and comparisons to competitors' results. We believe this measure is useful to investors in allowing for greater transparency related to supplemental information used in our financial and operational decision-making. Further, we believe that adjusted profit from continuing operations before income tax may be useful to investors as we are aware that certain of our significant shareholders utilize adjusted profit from continuing operations before income tax to evaluate our financial performance. Finally, adjusted profit from continuing operations before income tax is utilized in the calculation of other non-GAAP financial measures, which are used by the Compensation Committee of the Group's Board of Directors in assessing the performance and compensation of substantially all of our employees, including our executive officers.

There are limitations to using financial measures such as adjusted profit from continuing operations before income tax. Other companies in our industry may define adjusted profit from continuing operations before income tax differently than we do. As a result, it may be difficult to use adjusted profit from continuing operations before income tax or similarly named adjusted financial measures that other companies may use to compare the performance of those companies to our performance. Because of these limitations, adjusted profit from continuing operations before income tax is not intended to represent cash flow from operations as defined by U.S. GAAP and should not be used as an indicator of operating performance, a measure of liquidity or as alternative to net profit, cash flows or any other financial measure determined in accordance with U.S. GAAP. We compensate for these limitations by providing reconciliations of our total segment adjusted profit from continuing operations before income tax to our consolidated Loss from continuing operations before income tax, which is determined in accordance with U.S. GAAP and included in our Consolidated Profit and Loss Account.

Turnover. The following table displays our turnover by reportable segment for the years ended December 31, 2018 and 2017 (dollars in thousands):

			% Change
	2018	2017	2018 vs. 2017
U.S. Branded - Specialty & Established Pharmaceuticals	$ 862,832	$ 957,525	(10)%
U.S. Branded - Sterile Injectables	929,566	750,471	24 %
U.S. Generic Pharmaceuticals	1,012,215	1,530,530	(34)%
International Pharmaceuticals (1)	142,465	230,332	(38)%
Total net turnover from external customers	$ 2,947,078	$ 3,468,858	(15)%

(1) Turnover generated by our International Pharmaceuticals segment are primarily attributable to external customers located in Canada and, prior to the sale of Litha in July 2017 and Somar in October 2017, South Africa and Latin America.

U.S. Branded - Specialty & Established Pharmaceuticals. The following table displays the significant components of our U.S. Branded - Specialty & Established Pharmaceuticals turnover from external customers for the years ended December 31, 2018 and 2017 (dollars in thousands):

	2018	2017	% Change 2018 vs. 2017
Specialty Products:			
XIAFLEX®	$ 264,638	$ 213,378	24 %
SUPPRELIN® LA	81,707	86,211	(5)%
Other Specialty (1)	156,607	153,384	2 %
Total Specialty Products	$ 502,952	$ 452,973	11 %
Established Products:			
PERCOCET®	$ 122,901	$ 125,231	(2)%
VOLTAREN® Gel	57,700	68,780	(16)%
OPANA® ER	—	83,826	(100)%
Other Established (2)	179,279	226,715	(21)%
Total Established Products	$ 359,880	$ 504,552	(29)%
Total U.S. Branded - Specialty & Established Pharmaceuticals (3)	$ 862,832	$ 957,525	(10)%

(1) Products included within Other Specialty include NASCOBAL® Nasal Spray, TESTOPEL® and AVEED®.
(2) Products included within Other Established include, but are not limited to, LIDODERM®, FORTESTA® Gel, EDEX® and TESTIM® including the authorized generics of TESTIM® and FORTESTA® Gel.
(3) Individual products presented above represent the top two performing products in each product category and/or any product having turnover in excess of $100 million during any of the years ended December 31, 2018 and 2017 or $25 million during any quarterly period in 2018.

Specialty Products

The increase in net sales of XIAFLEX® in 2018 was primarily attributable to demand growth driven by the continued investment and promotional efforts behind XIAFLEX®, as well as price.

The decrease in net sales of SUPPRELIN® LA in 2018 was primarily attributable to decreased volume.

The increase in net sales of Other Specialty Products in 2018 was primarily attributable to increased sales of NASCOBAL® Nasal Spray and AVEED® due to improved volume. The increases in these products were partially offset by lower sales of TESTOPEL® due to decreases in both volume and price.

Established Products

The decrease in net sales of PERCOCET® in 2018 was primarily attributable to volume decreases, partially offset by price increases.

The decrease in net sales of VOLTAREN® Gel for 2018 was primarily attributable to price and volume decreases as a result of ongoing competitive pressure from generic competition. To the extent additional competitors launch generic versions of VOLTAREN® Gel, our turnover could decline further.

The decrease in net sales of OPANA® ER for 2018 relates primarily to our voluntary cessation of shipments of OPANA® ER to customers by September 1, 2017, as further described above.

Net sales of Other Established Products for 2018 were negatively impacted by volume decreases resulting from generic competition and certain other factors.

U.S. Branded - Sterile Injectables. The following table displays the significant components of our U.S. Branded - Sterile Injectables turnover from external customers for the years ended December 31, 2018 and 2017 (dollars in thousands):

	2018	2017	% Change 2018 vs. 2017
VASOSTRICT®	$ 453,767	$ 399,909	13%
ADRENALIN®	143,489	76,523	88%
Ertapenem for injection	57,668	—	NM
Other Sterile Injectables (1)	274,642	274,039	—%
Total U.S. Branded - Sterile Injectables (2)	$ 929,566	$ 750,471	24%

NM indicates that the percentage change is not meaningful or is greater than 100%.

(1) Products included within Other Sterile Injectables include, but are not limited to, APLISOL® and ephedrine sulfate injection.

(2) Individual products presented above represent the top two performing products for this segment and/or any product having turnover in excess of $100 million during any of the years ended December 31, 2018 and 2017 or $25 million during any quarterly period in 2018.

Net sales of VASOSTRICT® and ADRENALIN® increased in 2018 due to increases in both price and volume. Sales of ADRENALIN® also benefited from the market withdrawal of competing unapproved sources beginning in May of 2017. VASOSTRICT® is currently the first and only vasopressin injection with an NDA approved by the FDA. As of December 31, 2018, we have six patents for VASOSTRICT® listed in the Orange Book. We have additional patents pending with the PTO. The FDA requires any applicant seeking FDA approval for vasopressin prior to patent expiry and relying on VASOSTRICT® as the Reference Listed Drug to notify us of its filing before the FDA will issue an approval.

We are aware of certain competitive actions taken by other pharmaceutical companies related to VASOSTRICT®, which include the filing of ANDAs for generic versions of VASOSTRICT® and the commencement of bulk compounding of vasopressin, the active ingredient of VASOSTRICT®. These matters are further discussed in Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report under the heading "VASOSTRICT® Related Matters." We have taken and plan to continue to take actions in our best interest to protect our rights with respect to VASOSTRICT®. The introduction of any compounded or generic versions of VASOSTRICT® could result in reductions to our market share, turnover, profitability and cash flows.

Ertapenem for injection, the authorized generic of Invanz®, launched during the third quarter of 2018 and had no sales in 2017.

U.S. Generic Pharmaceuticals. Continued competitive pressure on commoditized generic products and the impact of product rationalization initiatives resulting from prior restructurings resulted in a turnover decrease in 2018. Additionally, included within this segment's turnover in 2017 are ezetimibe tablets and quetiapine ER tablets, both of which were first-to-file products launched in the fourth quarter of 2016. Combined net sales for these two products in 2017 were $250.2 million. The marketing exclusivity periods for both ezetimibe tablets and quetiapine ER tablets expired in the second quarter of 2017. As a result, combined turnover for these products declined significantly during the second quarter of 2017 and beyond. Partially offsetting the 2018 decrease was the impact of certain recent product launches including, among others, colchicine tablets, the authorized generic of Takeda Pharmaceuticals U.S.A., Inc.'s Colcrys®, which launched in July 2018.

International Pharmaceuticals. The decrease in turnover for the International Pharmaceuticals segment in 2018 was primarily attributable to the combined impact of our divestitures of Litha and Somar in the second half of 2017. The decrease in 2018 was partially offset by increases in turnover for certain other products within this segment. For additional detail regarding the divestitures of Litha and Somar refer to Note 3. Discontinued Operations and Divestitures of the accompanying Consolidated Financial Statements included in this report.

Adjusted profit from continuing operations before income tax. The following table displays our Adjusted profit from continuing operations before income tax by reportable segment for the years ended December 31, 2018 and 2017 (dollars in thousands):

	2018	2017	% Change 2018 vs. 2017
U.S. Branded - Specialty & Established Pharmaceuticals	$ 368,790	$ 485,515	(24)%
U.S. Branded - Sterile Injectables	695,363	563,103	23 %
U.S. Generic Pharmaceuticals	317,892	501,249	(37)%
International Pharmaceuticals	59,094	58,308	1 %
Total segment adjusted profit from continuing operations before income tax	$ 1,441,139	$ 1,608,175	(10)%

U.S. Branded - Specialty & Established Pharmaceuticals. Amounts were negatively impacted during 2018 as a result of decreased turnover and gross margins related to generic competition and the voluntary cessation of shipments of OPANA® ER by September 1, 2017. Additionally, in 2018, R&D expenses increased as a result of our cellulite treatment development program and legal costs related to certain litigation matters also increased. Our material legal proceedings and other contingent matters are described in more detail in Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in of this report.

U.S. Branded - Sterile Injectables. The increase in 2018 was primarily driven by increased turnover and gross margins resulting from strong performance of a variety of products in this segment as described above.

U.S. Generic Pharmaceuticals. The decrease in 2018 was primarily attributable to decreased turnover as described above and the resulting reduction to gross margin. Partially offsetting the decrease were the impacts of reductions to R&D and other operating expenses, including the impact of the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative and the January 2018 Restructuring Initiative, which are described more fully in Note 4. Restructuring of the accompanying Consolidated Financial Statements included in this report.

International Pharmaceuticals. Amounts were negatively impacted in 2018 as a result of the combined impact of our divestitures of Litha and Somar in the second half of 2017. This decrease in 2018 was more than offset by the gross margin effects of the turnover results of certain other International Pharmaceuticals products, as described above.

The table below provides reconciliations of our consolidated Total consolidated loss from continuing operations before income tax, which is determined in accordance with U.S. generally accepted accounting principles (U.S. GAAP), to our total segment adjusted profit from continuing operations before income tax for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Total consolidated loss from continuing operations before income tax	$ (938,832)	$ (1,483,004)
Interest expense, net	521,656	488,228
Corporate unallocated costs (1)	200,592	165,298
Amortization of intangible assets	622,339	773,766
Stock step-up and certain manufacturing costs that will be eliminated pursuant to integration plans	261	390
Upfront and milestone payments to partners	45,108	9,483
Separation benefits and other cost reduction initiatives (2)	86,295	212,448
Certain litigation-related and other contingencies, net (3)	13,809	185,990
Asset impairment charges (4)	916,939	1,154,376
Acquisition-related and integration items (5)	21,914	58,086
Loss on extinguishment of debt	—	51,734
Foreign currency impact related to the remeasurement of intercompany debt instruments	(5,486)	(1,403)
Other, net (6)	(43,456)	(7,217)
Total segment adjusted profit from continuing operations before income tax	$ 1,441,139	$ 1,608,175

(1) Amounts include certain corporate overhead costs, such as headcount, facility and corporate litigation expenses and certain other income and expenses.

(2) Amounts in 2018 primarily relate to employee separation costs of $31.7 million, accelerated depreciation of $35.2 million, charges to increase excess stock reserves of $2.9 million and other charges of $16.5 million, each of which related primarily to our restructuring initiatives. Amounts in 2017 primarily relate to employee separation costs of $53.0 million, accelerated depreciation of $123.7 million, charges to increase excess stock reserves of $13.7 million and other charges of $22.0 million. These charges were related primarily to the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative. See Note 4. Restructuring of the accompanying Consolidated Financial Statements included in this report for discussion of our material restructuring initiatives.

(3) Amounts include adjustments for Litigation-related and other contingencies, net as further described in Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report.

(4) Amounts primarily relate to charges to impair goodwill and intangible assets as further described in Note 9. Goodwill and Other Intangibles as well as charges to write down certain tangible fixed assets as further described in Note 4. Restructuring, Note 6. Fair Value Measurements and Note 8. Tangible Fixed Assets of the accompanying Consolidated Financial Statements included in this report.

(5) Amounts include charges due to changes in the fair value of contingent consideration of $19.9 million and $49.9 million, respectively. All other amounts are directly related to costs associated with acquisition and integration efforts.

(6) Amounts in 2018 primarily relate to gains on sales of businesses and other assets, as further described in Note 17. Other Income, Net of the accompanying Consolidated Financial Statements included in this report.

Liquidity and Capital Resources

Our principal source of liquidity is cash generated from operations. Our principal liquidity requirements are primarily for working capital for operations, licenses, milestone payments, capital expenditures, acquisitions, contingent liabilities, vaginal mesh liability payments and debt service payments. The Group's working capital was $393.1 million at December 31, 2018 compared to working capital of $50.2 million at December 31, 2017. The amounts at December 31, 2018 and December 31, 2017 include restricted cash at bank and in-hand of $299.7 million and $313.8 million, respectively, held in QSFs for mesh-related matters. Although these amounts in QSFs are included in working capital, they are required to be used for mesh product liability settlement agreements that are expected to be paid to qualified claimants within the next twelve months.

Cash at bank and in-hand, which primarily consisted of bank deposits, time deposits and money market accounts, totaled $1,149.1 million at December 31, 2018 compared to $986.6 million at December 31, 2017. We expect cash generated from operations together with our cash at bank and in-hand, restricted cash at bank and in-hand and the revolving credit facilities to be sufficient to cover our principal liquidity requirements over the next year. However, on a longer term basis, we may not be able to accurately predict the effect of certain developments on our sales and gross margins, such as the degree of market acceptance, patent protection and exclusivity of our products, pricing pressures (including those due to the impact of competition), the effectiveness of our sales and marketing efforts and the outcome of our current efforts to develop, receive approval for and successfully launch our product candidates. We may also face unexpected expenses in connection with our business operations, including expenses related to our ongoing and future legal proceedings and governmental investigations and other contingent liabilities. Furthermore, we may not be successful in implementing, or may face unexpected changes or expenses in connection with our strategic direction, including the potential for opportunistic corporate development transactions. Any of the above could adversely affect our future cash flows.

From time to time, we may seek to enter into certain transactions to reduce the extent of our leverage and/or interest expense and/or to extend the maturities of our outstanding indebtedness. Such transactions could include, for example, transactions to exchange existing indebtedness for our ordinary shares, to issue equity (including convertible securities) or to repurchase, redeem or refinance our existing indebtedness (including the Credit Agreement). In order to finance any such transactions, we may need to obtain additional funding. Any of these transactions could impact our liquidity.

We may also require additional financing to fund our future operational needs or for future corporate transactions, including acquisitions. We have historically had broad access to financial markets that provide liquidity; however, we cannot be certain that funding will be available to us in the future on terms acceptable to us, or at all. Any issuances of equity securities or convertible securities, in connection with an acquisition or otherwise, could have a dilutive effect on the ownership interest of our current shareholders and may adversely impact net profit per share in future periods. An acquisition may be accretive or dilutive and, by its nature, involves numerous risks and uncertainties. As a result of acquisition efforts, if any, we are likely to experience significant charges to earnings for merger and related expenses (whether or not the acquisitions are consummated) that may include transaction costs, closure costs or costs of restructuring activities.

We consider the undistributed earnings from the majority of our subsidiaries as of December 31, 2018 to be indefinitely reinvested outside of Ireland and, accordingly, neither income tax nor withholding taxes have been provided thereon. As of December 31, 2018, indefinitely reinvested earnings were approximately $1,231.8 million. We do not anticipate incurring tax in deploying funds to satisfy liquidity needs arising in the ordinary course of our business.

Borrowings. The Group and certain of its subsidiaries are party to: (i) a credit agreement (the Credit Agreement), which provides for a senior secured revolving credit facility (the Revolving Credit Facility) and a senior secured term loan facility (the Term Loan Facility and, together with the Revolving Credit Facility, the Credit Facilities) and (ii) the indenture governing our senior secured notes (the 5.875% Senior Secured Notes due 2024, referred to as the 2024 Notes). Certain subsidiaries of the Group are also party to the indentures governing our various senior unsecured notes. At December 31, 2018, an aggregate principal amount of $3.4 billion is outstanding under the Term Loan Facility, $5.0 billion is outstanding under the senior unsecured notes and senior secured notes and approximately $997.3 million is available under the Revolving Credit Facility.

The obligations of the borrowers under the Credit Agreement are guaranteed by the Group and the subsidiaries of the Group (with certain customary exceptions). The Credit Agreement contains affirmative and negative covenants that the Group believes to be usual and customary for a senior secured credit facility of this type. The negative covenants include, among other things, limitations on asset sales, mergers and acquisitions, indebtedness, liens, dividends and other restricted payments, investments and transactions with the Group's affiliates. As of December 31, 2018 and 2017, we were in compliance with all such covenants. In addition, on an annual basis commencing with the year ended December 31, 2018, the Group is required to perform a calculation of Excess Cash Flow (as defined in the Credit Agreement), which could result in certain pre-payments of the principal relating to the Term Loan Facility in accordance with the terms of the Credit Agreement. No such payment is required at December 31, 2018.

The Group's notes mature between 2022 and 2025, subject to earlier repurchase or redemption in accordance with the terms of the respective indentures. Interest rates on these notes range from 5.375% to 7.25%. Other than the 2024 Notes, these notes are senior unsecured obligations of the Group's subsidiaries party to the applicable indentures governing such notes. These notes are issued by certain of the Group's subsidiaries and are guaranteed on a senior unsecured basis by the subsidiaries of Endo International plc that also guarantee the Credit Agreement, except for a de minimis amount of the 7.25% Senior Notes due 2022, which are issued by EHSI and guaranteed on a senior unsecured basis by the guarantors named in the Fifth Supplemental Indenture relating to such notes. The 2024 Notes are senior secured obligations of Endo International plc and its subsidiaries that are party to the indenture governing such notes. These notes are issued by certain of our subsidiaries and are guaranteed on a senior secured basis by Endo International plc and its subsidiaries that also guarantee our Credit Agreement.

The indentures governing our various senior notes contain affirmative and negative covenants that the Group believes to be usual and customary for similar indentures. Under the senior secured notes indenture, the negative covenants, among other things, restrict the Group's ability, and the ability of its restricted subsidiaries, to incur certain additional indebtedness and issue preferred stock, make certain dividends, distributions, investments and other restricted payments, sell certain assets, enter into sale and leaseback transactions, agree to payment restrictions on the ability of restricted subsidiaries to make certain payments to Endo International plc or any of its restricted subsidiaries, create certain liens, merge, consolidate or sell all or substantially all of the Group's or guarantors' assets, enter into certain transactions with affiliates or designate subsidiaries as unrestricted subsidiaries. Under the senior unsecured notes indentures, the negative covenants, among other things, restrict the ability of Endo Designated Activity Company and its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock, make certain dividends, distributions, investments and other restricted payments, sell certain assets, enter into sale and leaseback transactions, agree to payment restrictions on the ability of restricted subsidiaries to make certain payments to the issuer or any of the restricted subsidiaries, create certain liens, merge, consolidate or sell all or substantially all of Endo Designated Activity Company's, its co-issuers' or guarantors' assets, enter into certain transactions with affiliates or designate subsidiaries as unrestricted subsidiaries. These covenants are subject to a number of exceptions and qualifications, including the fall away or revision of certain of these covenants, and release of collateral in the case of the 2024 Notes, upon the notes receiving investment grade credit ratings. As of December 31, 2018 and 2017, we were in compliance with all such covenants.

The obligations under (i) the Credit Agreement and related loan documents and (ii) the indenture governing the 2024 Notes and related documents are secured on a *pari passu* basis by a perfected first priority (subject to certain permitted liens) lien on substantially all of the assets of the borrowers and the guarantors (subject to customary exceptions).

Credit ratings. The Group's corporate credit ratings assigned by Moody's Investors Service and Standard & Poor's are B2 with a negative outlook and B with a stable outlook, respectively.

Working capital. The components of our working capital and our liquidity at December 31, 2018 and December 31, 2017 are below (dollars in thousands):

	December 31, 2018	December 31, 2017
Total current assets	$ 2,343,150	$ 2,271,077
Less: total current liabilities	(1,950,096)	(2,220,909)
Working capital	$ 393,054	$ 50,168
Current ratio (total current assets divided by total current liabilities)	1.2:1	1.0:1

Net working capital increased by $342.9 million from December 31, 2017 to December 31, 2018. This increase primarily reflects the favorable impact to net current assets resulting from operations during the year ended December 31, 2018. Working capital also increased as a result of net 2018 proceeds of $23.1 million from our sale of our Huntsville facilities and $34.3 million from our sales of various ANDAs. These increases were partially offset by certain items including, but not limited to, the working capital effect of net decreases in long-term litigation-related liabilities of $210.5 million, purchases of tangible fixed assets, excluding capitalized interest, of $83.4 million and net decreases in the aggregate principal amount of noncurrent debt of $34.2 million.

The following table summarizes our Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017
Net cash flow provided by (used in):		
Operating activities	$ 267,270	$ 553,985
Investing activities	(17,900)	104,583
Financing activities	(81,572)	(166,993)
Effect of foreign exchange rate	(1,975)	2,515
Movement in cash held for sale	—	11,744
Net increase in cash at bank an in-hand and restricted cash at bank and in-hand	$ 165,823	$ 505,834

Operating activities. Net cash provided by operating activities represents the cash receipts and cash disbursements from all of our activities other than investing activities and financing activities. Changes in cash from operating activities reflect, among other things, the timing of cash collections from customers, payments to suppliers, managed care organizations, government agencies, collaborative partners and employees, as well as tax payments and refunds in the ordinary course of business.

The $286.7 million decrease in Net cash provided by operating activities in 2018 compared to 2017 was primarily the result of the timing of cash collections and cash payments related to our operations. In particular, net sales of ezetimibe tablets and quetiapine ER tablets, which were launched in the fourth quarter of 2016 and for which the marketing exclusivity periods expired in the second quarter of 2017, generated significant cash receipts during 2017 that did not reoccur during 2018. Additionally, cash paid for interest in 2018 increased as compared to 2017 as a result of changes in interest rates. These decreases to Net cash provided by operating activities were partially offset by a decline in cash outlays for mesh settlements, which decreased $273.2 million in 2018 as compared to 2017.

Investing activities. The $122.5 million change in Net cash (used in) provided by investing activities for 2018 compared to 2017 reflects a decrease in net proceeds from the sales of businesses and other assets of $152.9 million. Amounts during 2018 primarily relate to proceeds from the sales of various ANDAs, proceeds from the sale of our Huntsville facilities and additional proceeds received in 2018 from our 2017 sale of Litha. Amounts during 2017 primarily relate to our sales of Litha, Somar and our Charlotte facilities. Also contributing to the change in Net cash (used in) provided by investing activities was a decrease in proceeds from notes receivable of $7.0 million during 2018 as compared to 2017. These items were partially offset by a decrease in purchases of tangible fixed assets, excluding capitalized interest of $42.3 million.

Financing activities. The $85.4 million decrease in Net cash used in financing activities in 2018 as compared to 2017 reflects a decrease in principal payments on term loans of $3,696.8 million, a decrease in deferred financing fees of $57.8 million and a decrease in payments for contingent consideration of $47.3 million, partially offset by a decrease in proceeds from issuance of term loans of $3,415.0 million and a decrease in proceeds from issuance of notes of $300.0 million.

Research and development. Over the past few years, we have incurred significant expenditures related to conducting clinical studies to develop new products and expand the value of our existing products beyond their currently approved indications.

For example, as further described above under the heading “Results of Operations,” the Group has recently incurred R&D expense for certain indications of CCH in various stages of development.

We expect to incur R&D expenditures related to the development and advancement of our current generic and branded product pipeline and any additional product candidates we may add via license, acquisition or organically. There can be no assurance that the results of any ongoing or future nonclinical or clinical trials related to these projects will be successful, that additional trials will not be required, that any drug, product or indication under development will receive regulatory approval in a timely manner or at all or that such drug, product or indication could be successfully manufactured in accordance with local current good manufacturing practices or marketed successfully, or that we will have sufficient funds to develop or commercialize any of our products.

Manufacturing, supply and other service agreements. We contract with various third party manufacturers, suppliers and service providers to supply our products, or materials used in the manufacturing of our products, and to provide additional services such as packaging, processing, labeling, warehousing, distribution and customer service support. Any interruption to the goods or services provided for by these and similar contracts could have an adverse effect on our business, financial condition, results of operations and cash flows.

License and collaboration agreements. We could become obligated to make certain contingent payments pursuant to our license, collaboration and other agreements. Payments under these agreements generally become due and payable only upon the achievement of certain developmental, regulatory, commercial and/or other milestones. In addition, we may be required to make sales-based royalty payments under certain arrangements if certain products are approved for marketing. Due to the fact that it is uncertain whether and when certain of these milestones will be achieved, they have not been recorded in our Consolidated Balance Sheets.

Acquisitions. Going forward, our primary focus will be on organic growth. However, we may consider and, as appropriate, make acquisitions of other businesses, products, product rights or technologies. Our cash reserves and other liquid assets may be inadequate to consummate such acquisitions and it may be necessary for us to issue ordinary shares or raise substantial additional funds in the future to complete future transactions. In addition, as a result of any acquisition efforts, we are likely to experience significant charges to earnings for merger and related expenses (whether or not our efforts are successful) that may include transaction costs, closure costs, integration costs and/or costs of restructuring activities.

Legal proceedings. We are subject to various patent challenges, product liability claims, government investigations and other legal proceedings in the ordinary course of business. Contingent accruals are recorded when we determine that a loss is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgments regarding future events. For additional discussion of legal proceedings, see Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report.

Contractual Obligations. The following table lists our enforceable and legally binding noncancelable obligations as of December 31, 2018:

	Payment Due by Period (in thousands)						
	Total	2019	2020	2021	2022	2023	Thereafter
Long-term debt obligations (1)	$ 8,348,775	$ 34,150	$ 34,150	$ 34,150	$ 1,134,150	$ 2,419,150	$ 4,693,025
Interest expense (2)	2,774,109	543,359	544,821	541,653	500,520	441,581	202,175
Capital lease obligations (3)	44,048	6,884	6,819	6,921	7,072	7,225	9,127
Operating lease obligations (4)	86,174	15,800	14,519	12,883	12,454	9,945	20,573
Purchase obligations (5)	69,641	27,483	16,068	12,731	1,937	1,719	9,703
Mesh-related product liability settlements (6)	258,051	258,051	—	—	—	—	—
Other obligations and commitments (7)	5,833	2,833	500	500	500	500	1,000
Total (8)	$ 11,586,631	$ 888,560	$ 616,877	$ 608,838	$ 1,656,633	$ 2,880,120	$ 4,935,603

(1) Includes minimum cash payments related to principal associated with our indebtedness as of December 31, 2018. A discussion of such indebtedness is included above under the caption "Borrowings." The amounts in this table do not reflect any potential early or accelerated principal payments such as the potential payments described in Note 12. Debt of the accompanying Consolidated Financial Statements included in this report.

(2) These amounts represent future cash interest payments related to our indebtedness as of December 31, 2018 based on interest rates specified in the associated debt agreements. Payments related to variable-rate debt are based on applicable market rates, estimated at December 31, 2018, plus the specified margin in the associated debt agreements for each period presented.

(3) Includes minimum cash payments related to certain fixed assets, primarily related to technology. In addition, includes minimum cash payments related to the direct financing arrangement for our U.S. headquarters in Malvern, Pennsylvania. We have entered into agreements to sublease certain properties. Most significantly, we sublease approximately 140,000 square feet of our Malvern, Pennsylvania headquarters and substantially all of our Chesterbrook, Pennsylvania facility. As of December 31, 2018, we expect to receive approximately $29.7 million in future minimum rental payments over the remaining terms of the Malvern and Chesterbrook subleases from 2019 until 2024. Amounts included in this table have not been reduced by the minimum sublease rentals.

(4) Includes minimum cash payments related to our leased automobiles, machinery and equipment, facilities and other property not included in capital lease obligations. Any proceeds for sublease income are excluded from the table above.

(5) Purchase obligations are enforceable and legally binding obligations for purchases of goods and services, including minimum stock contracts.

(6) The amounts included above represent contractual payments for mesh-related product liability settlements and reflect the earliest date that a settlement payment could be due and the largest amount that could be due on that date. These matters are described in more detail in Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report.
(7) Other obligations and commitments include agreements to purchase third-party assets, products and services and other minimum royalty obligations.
(8) Total generally does not include contractual obligations already included in current liabilities on our Consolidated Balance Sheets, except for current portion of long-term debt, accrued interest, short-term capital lease obligations, mesh-related product liabilities and certain purchase obligations, which are discussed below.

For purposes of the table above, obligations for the purchase of goods or services are included only for significant noncancelable purchase orders at least one year in length that are enforceable, legally binding and specify all significant terms, including fixed or minimum quantities to be purchased, fixed, minimum or variable price provisions and the timing of the obligation. In cases where our minimum obligations are variable based on future contingent events or circumstances, we estimate the minimum obligations based on information available to us at the time of disclosure. Our purchase orders are based on our current manufacturing needs and are typically fulfilled by our suppliers within a relatively short period. At December 31, 2018, we have open purchase orders that represent authorizations to purchase, rather than binding agreements, that are not included in the table above. In addition, we do not include collaboration agreements and potential payments under those agreements or potential payments related to contingent consideration.

Information about our liability for unrecognized tax benefits is included in Note 18. Income Taxes of the accompanying Consolidated Financial Statements included in this report under the caption "Uncertain Tax Positions." Due to the nature and timing of the ultimate outcome of these uncertain tax positions, we cannot make a reliable estimate of the amount and period of related future payments. Therefore, our liability has been excluded from the above contractual obligations table.

Fluctuations. Our quarterly results have fluctuated in the past and may continue to fluctuate. These fluctuations may be due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing, certain actions taken by us which may impact the availability of our products, asset impairment charges, litigation-related charges, restructuring costs, including separation benefits, business combination transaction costs, upfront, milestone and certain other payments made or accrued pursuant to licensing agreements and changes in the fair value of financial instruments and contingent assets and liabilities recorded as part of business combinations. Further, a substantial portion of our total turnover is through three wholesale drug distributors who in turn supply our products to pharmacies, hospitals and physicians. Accordingly, we are potentially subject to a concentration of credit risk with respect to our trade receivables.

Growth opportunities. We continue to evaluate growth opportunities including investments, licensing arrangements, acquisitions of product rights or technologies, businesses and strategic alliances and promotional arrangements, any of which could require significant capital resources. We continue to focus our business development activities on further diversifying our turnover base through product licensing and company acquisitions, as well as other opportunities to enhance shareholder value. Through execution of our business strategy, we focus on developing new products both internally and with contract and collaborative partners; expanding our product lines by acquiring new products and technologies, increasing turnover and earnings through sales and marketing programs for our innovative product offerings and effectively using our resources; and providing additional resources to support our businesses.

Non-U.S. operations. Fluctuations in foreign currency rates resulted in a net gain of $3.8 million in 2018 and a net gain of $2.8 million in 2017.

Inflation. We do not believe that inflation had a material adverse effect on our financial statements for the periods presented.

Off-balance sheet arrangements. We have no off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Financial Risk Management

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our variable-rate indebtedness associated with our Term Loan Facility and Revolving Credit Facility. At both December 31, 2018 and 2017, the aggregate principal amount of such variable-rate indebtedness was $3.4 billion. Borrowings under the Credit Agreement may from time to time bear interest at variable rates, which rates are further described in Note 12. Debt of the accompanying Consolidated Financial Statements included in this report, in certain cases subject to a floor. At December 31, 2018 and 2017, a hypothetical 1% increase in the applicable rate over the floor would have resulted in $33.6 million and $34.0 million, respectively, of incremental annual interest expense related to our variable-rate debt borrowings.

To the extent that we utilize amounts under the Revolving Credit Facility or take on additional variable rate indebtedness, we will be exposed to additional interest rate risk.

As of December 31, 2018 and 2017, we had no other assets or liabilities with significant interest rate sensitivity.

Foreign Currency Exchange Risk

We operate and transact business in various foreign countries and are therefore subject to risks associated with foreign currency exchange rate fluctuations. The Group manages this foreign currency risk, in part, through operational means including managing foreign currency turnover in relation to same currency costs as well as managing foreign currency assets in relation to same currency liabilities. The Group is also exposed to the potential earnings effects from intercompany foreign currency assets and liabilities that arise from normal trade receivables and payables and other intercompany loans. Additionally, certain of the Group's subsidiaries maintain their books of record in currencies other than their respective functional currencies. These subsidiaries' financial statements are remeasured into their respective functional currencies using current or historic exchange rates. Such remeasurement adjustments could have an adverse effect on the Group's results of operations.

All assets and liabilities of our international subsidiaries, which maintain their financial statements in local currency, are translated to U.S. dollars at period-end exchange rates. Translation adjustments arising from the use of differing exchange rates are included in Accumulated other comprehensive loss. Gains and losses on foreign currency transactions and short-term intercompany receivables from foreign subsidiaries are included in Other income, net.

Fluctuations in foreign currency rates resulted in a net gain of $3.8 million in 2018 and a net gain of $2.8 million in 2017.

Based on the Group's significant foreign currency denominated intercompany loans existing at December 31, 2018 and 2017, we estimate that a 10% change in the underlying currencies of our foreign currency denominated intercompany loans, relative to the U.S. Dollar, could have resulted in approximately $9 million and $10 million in incremental foreign currency losses, respectively.

Principal Risks

We operate in a highly competitive industry.

The pharmaceutical industry is intensely competitive and we face competition in both our domestic and international branded and generic pharmaceutical business. In addition to product development and technological innovation, safety, efficacy, commercialization, marketing and promotion, other competitive factors include product quality and price, cost-effectiveness, reputation, service and patient convenience and access to scientific and technical information. Many of our competitors, including Teva, Mylan, Sandoz, Amneal, Allergan, Purdue, Jazz, Takeda, Horizon and Mallinckrodt, among others, and any future companies that may enter the industry or modify their existing products to compete directly with our products, may have greater resources than we do and we cannot predict with certainty the timing or impact of competitors' products and commercialization strategies. Furthermore, recent trends in this industry are toward further market consolidation of large drug companies into a smaller number of very large entities, further concentrating financial, technical and market strength and increasing competitive pressure in the industry. It is possible that our competitors may make greater research and development investments and have more efficient or superior processes and systems and more experience in the development of new products that permit our competitors to respond more quickly to new or emerging technologies and changes in customer requirements which may make our products or technologies uncompetitive or obsolete. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection and may establish collaborative arrangements for competitive products or programs. If we fail to compete successfully, our business, results of operations, financial condition and cash flows could be materially adversely affected.

Our branded products face competition from generic versions. Such versions are generally significantly cheaper than branded versions and, where available, may be required or encouraged in place of the branded version under third-party reimbursement programs, or required by law to be substituted by pharmacies for branded versions. The entrance of such competition to our branded products generally reduces our market share and adversely affects our profitability and cash flows. Further, certain Asian and other overseas generic competitors may be able to produce products at costs lower than the costs of domestic manufacturers. If we experience substantial competition from Asian or other overseas generic competitors with lower production costs, our profit margins will suffer. In addition, certain of our branded products are not protected by patent rights or have limited patent life and will soon lose patent protection. Loss of patent protection for a branded product typically is followed promptly by generic substitutes. As a result, sales of many of these branded products may decline or stop growing over time. Generic competition with our branded products has had and will continue to have a material adverse effect on the market share, net sales and profitability of our branded products. In addition, legislative proposals emerge from time to time in various jurisdictions to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could increase competition and worsen this negative effect on our sales and profitability.

In addition, our generics business faces competition from brand-name pharmaceutical companies, which have taken aggressive steps to thwart or delay competition from generic equivalents of their brand-name products, including bringing litigation alleging patent infringement or other violation of intellectual property rights. The actions taken by competing brand name pharmaceutical companies may increase the costs and risks associated with our efforts to introduce generic products and may delay or prevent such introduction altogether. For example, if a brand-name pharmaceutical company's patent was held to be valid and infringed by our generic products in a particular jurisdiction, we would be required to either obtain a license from the patent holder or cease the manufacture and sale of such generic product.

Our sales may also suffer as a result of changes in consumer demand for our products, including those related to fluctuations in consumer buying patterns tied to seasonality or the introduction of new products by competitors, which could have a material adverse effect on our business, results of operations, financial condition and cash flows. Additionally, a significant portion of our turnover from our branded businesses are derived from a limited number of products. The sale of our products can be significantly influenced by market conditions and regulatory actions. We may experience decreases in the sale of our products in the future as a result of actions taken by our competitors, such as price reductions, or as a result of regulatory actions related to our products or to competing products. A decline in the sales value of these products could have a material adverse effect on our business, results of operations, financial condition and cash flows.

If other pharmaceutical companies use litigation and regulatory means to obtain approval for generic, over-the-counter or other competing versions of our drugs, our sales may suffer.

Under the Hatch-Waxman Act, the FDA can approve an Abbreviated New Drug Application ("ANDA") for a generic bioequivalent version of a previously approved drug without requiring the ANDA applicant to undertake the full clinical testing necessary to obtain approval to market a new branded drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its generic product is the same as the referenced listed drug with respect to the active ingredient and is bioequivalent to the branded product. Over-the-counter ("OTC") drugs may be developed under either the New Drug Applications ("NDA") or OTC monograph process. The OTC monograph process allows for OTC products to be marketed without pre-market approval and generally does not require clinical studies.

Various manufacturers have filed ANDAs seeking FDA approval for generic versions of certain of our key pharmaceutical products including, but not limited to, LIDODERM®, VASOSTRICT® and AVEED®. In connection with such filings, these manufacturers have challenged the validity and/or enforceability of one or more of the underlying patents protecting our products. In the case of LIDODERM®, we no longer have patent protection in the markets where we sell these products. Our revenues from LIDODERM® have been negatively affected by multiple competing generic versions of LIDODERM®, the first of which launched in September 2013. We anticipate that these revenues could decrease further should one or more additional generic versions of LIDODERM® launch.

Additionally, we recently received notice from a competing pharmaceutical company that manufactures one of our products that it intends to seek approval to launch a competing OTC version of such product. We are currently assessing the potential likelihood, timing and impact of any such launch, which could result in, among other things, a reduction of our net sales of such product and/or certain asset impairment charges that could be material. We cannot assure you that this, or any other manufacturer, will not take similar actions with respect to other products.

With respect to AVEED®, VASOSTRICT® and other branded pharmaceutical products, it has been and continues to be our practice to vigorously defend and pursue all available legal and regulatory avenues in defense of the intellectual property rights protecting our products. Despite our efforts to defend our products, litigation is inherently uncertain, and we cannot predict the timing or outcome of our efforts. If we are not successful in defending our intellectual property rights or opt to settle, or if a product's marketing exclusivity rights expire or become otherwise unenforceable, our competitors could ultimately launch generic, OTC or other competing versions of our products, which would likely cause sales and revenues of the affected products to decline rapidly and materially, could require us to write off a portion or all of the intangible assets associated with the affected product and could have a material adverse effect on our business, results of operations, financial condition and cash flows.

In the case of VASOSTRICT®, Par Sterile Products, LLC ("PSP") and Par Pharmaceutical, Inc. ("PPI") received a notice letter from Eagle Pharmaceuticals, Inc. ("Eagle") in April 2018 advising of the filing by such company of an ANDA for a generic version of VASOSTRICT® (vasopressin IV solution (infusion)). The Paragraph IV notice refers to patents the Company has listed in the Orange Book covering either vasopressin-containing pharmaceutical compositions or methods of using a vasopressin-containing dosage form to increase blood pressure in humans. In May 2018, PPI, PSP and Endo Par Innovation Company, LLC ("EPIC") filed a lawsuit against Eagle in the United States District Court for the District of

Delaware within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. We intend to vigorously defend VASOSTRICT®'s intellectual property rights and to pursue all available legal, business and regulatory avenues in defense of VASOSTRICT®, including enforcement of the product's intellectual property rights. However, there can be no assurance that our defense will be successful. If a generic version of VASOSTRICT® were introduced to the market before 2020, our revenues from VASOSTRICT® would decrease significantly and, depending on the timing of such introduction and its effect on VASOSTRICT® pricing, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

There are currently ongoing legal proceedings brought by us and/or our subsidiaries, and in certain cases our third party partners, against manufacturers seeking FDA approval for generic versions of our products. For a description of the material related legal proceedings, see Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report.

We also believe it is likely that manufacturers may seek FDA approvals for generic, OTC or other competing versions of other of our key pharmaceutical products, either through the filing of ANDAs, through the OTC monograph process or the use of other means.

If pharmacies or outsourcing facilities produce compounded versions of our products, our sales may suffer.

Under section 503A of the FFDCA, licensed pharmacies may sell compounded versions of prescription drugs that have been prepared for individual patients based on the receipt of a valid prescription order or notation. Similarly, under section 503B of the FFDCA, outsourcing facilities may sell compounded versions of prescription drugs to healthcare providers. In January 2017, the FDA revised its policy to allow outsourcing facilities to "nominate" bulk drug substances that can be used to prepare compounded drugs under section 503B, although that policy is the subject of a pending legal challenge by us. Compounded drugs do not typically require the same R&D investments as either branded or generic drugs and, therefore, can compete favorably on price with both branded and generic versions of a drug. To the extent that pharmacies or outsourcing facilities introduce compounded versions of our products, our market share could be reduced and our profitability and cash flows could be adversely affected.

If we fail to successfully identify and develop additional generic pharmaceutical products, obtain exclusive marketing rights for our generic products or fail to introduce these generic products on a timely basis, our turnover, gross margin and operating results may decline.

We may not be successful in our efforts to continue to create a pipeline of product candidates or develop commercially successful products. Identifying, developing and obtaining regulatory approval and commercializing additional product candidates is prone to risks of failure inherent in drug development. For example, our research programs may initially show promise in identifying potential additional product candidates, yet fail to yield results for a number of reasons, including, among others, that the research methodology used may not be successful. No assurance can be given that we will be able to successfully identify additional product candidates, advance any additional product candidates through the development process or successfully commercialize any such additional product candidates. If we are unable to successfully identify, develop and commercialize additional product candidates, our turnover and operating results may decline significantly and our prospects and business may be materially adversely affected.

Even if we are able to identify and develop additional product candidates, we may fail to obtain exclusive marketing rights for such product candidates or fail to introduce such product candidates on a timely basis. Subject to certain exceptions and limitations, the Hatch-Waxman amendments to the FFDCA provide for a period of 180 days of marketing exclusivity for a generic version of a previously approved drug for any applicant that is the first to file an ANDA containing a Paragraph IV certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to the corresponding brand-name drug. Our turnover has historically included and may from time to time continue to include sales of generic drugs with limited competition resulting from this 180-day marketing exclusivity period or other factors, and the amounts of such turnover may be material. ANDAs that contain Paragraph IV certifications challenging patents generally become the subject of patent litigation that can be both lengthy and costly. There is no certainty that we will prevail in any such litigation, that we will be the first to file and be granted the 180-day marketing exclusivity period or, if we are granted the 180-day marketing exclusivity period, that we will not forfeit such period. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other ANDA applicants who submit Paragraph IV certifications. In addition, brand-name pharmaceutical companies often authorize a generic version of the corresponding brand-name drug to be sold during any period of marketing exclusivity that is awarded. Authorized generics are not prohibited from sale during the 180-day marketing exclusivity period. Furthermore, timely commencement of the litigation by the patent owner imposes an automatic stay of ANDA approval by the FDA for 30 months unless the case is decided in the ANDA applicant's favor during that period. Finally, if the court decision is adverse to the ANDA applicant, the ANDA approval will be delayed until the challenged patent expires and the applicant will not be granted 180 days of marketing exclusivity.

Our future profitability depends, to a significant extent, upon our ability to introduce, on a timely basis, new generic products that are either the first-to-market (or among the first-to-market) or that otherwise can gain significant market share during this 180-day marketing exclusivity period. Our ability to timely bring new generic products to market is dependent upon, among other things, the timing of regulatory approval of such products that, to a large extent, is outside of our control. Our turnover and future profitability are dependent, in large part, upon our ability or the ability of our development partners to file, timely and effectively, ANDAs with the FDA or similar filings with other regulatory agencies, or to enter into contractual relationships with other parties that have obtained marketing exclusivity, as well as the timing and extent of the commercialization by others of competing products. No assurances can be given that we will be able to develop and introduce commercially successful products in the future within the time constraints necessary to be successful. If we and/or our development partners are unable to continue to timely and effectively file ANDAs with the FDA or similar filings with other regulatory agencies, or to partner with other parties that have obtained marketing exclusivity, our turnover and operating results may decline significantly and our prospects and business may be materially adversely affected.

We have been, continue to be and may be the subject of lawsuits, product liability claims, other significant legal proceedings, government investigations or product recalls for which we may be unable to obtain or maintain insurance adequate to cover potential liabilities.

Our business exposes us to significant potential risks from lawsuits, product liability claims, other significant legal proceedings, government investigations or product recalls, including, but not limited to, such matters associated with the testing, manufacturing, marketing and sale of our products. Some plaintiffs have received substantial damage awards in some jurisdictions against healthcare companies based upon various legal theories, including without limitation claims for injuries allegedly caused by the use of their products. We have been, continue to be and may be subject to various product liability cases, as well as other significant legal proceedings and government investigations.

For example, we and our subsidiaries, along with other manufacturers of prescription opioid medications, are the subject of lawsuits and have received subpoenas and other requests for information from various state and local government agencies regarding the sale, marketing and/or distribution of prescription opioid medications. Numerous claims against opioid manufacturers have been and may continue to be filed by or on behalf of states, counties, cities, Native American tribes, other government-related persons or entities, hospitals, health systems, unions, health and welfare funds, other third-party payers and/or individuals. See Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report for more information. In these cases, plaintiffs seek various remedies, including without limitation declaratory and/or injunctive relief; compensatory, punitive and/or treble damages; restitution, disgorgement, civil penalties, abatement, attorneys' fees, costs and/or other relief. In addition to direct expenditures for damages, settlement and defense costs in connection with these claims, proceedings and investigations, there is a possibility of loss of revenues, injunctions and disruption of business. Furthermore, we and other manufacturers of prescription opioid medications have been, and will likely continue to be, subject to negative publicity and press, which could harm our brand and the demand for our products. There are also regulatory and legislative proposals being made that could impact us and other manufacturers of prescription opioid medications. See the principal risk "Our business and financial condition may be adversely affected by legislation" for more information.

Our current and former products may cause, or may appear to cause, serious adverse side effects or potentially dangerous drug interactions if misused or improperly prescribed or as a result of faulty surgical technique. For example, we and/or certain of our subsidiaries and certain other manufacturers have been named as defendants in multiple lawsuits in various federal and state courts alleging personal injury resulting from use of transvaginal surgical mesh products designed to treat pelvic organ prolapse (POP) and stress urinary incontinence. The U.S. Food and Drug Administration ("FDA") held a public advisory committee meeting in February 2019 during which the members of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee discussed and made recommendations regarding the safety and effectiveness of surgical mesh to treat POP. In April 2019, following the meeting, the FDA ordered that the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair of POP to cease selling and distributing their products in the U.S. effective immediately. Although we have not sold transvaginal surgical mesh products since March 2016, it is possible that the FDA's order and any additional FDA actions based on the outcome of the advisory committee meeting could result in additional litigation against the Company. See Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report for more information.

Any failure to effectively identify, analyze, report and protect adverse event data and/or to fully comply with relevant laws, rules and regulations around adverse event reporting could expose the Company to penalties, fines and reputational damage.

In addition, in the age of social media, plaintiffs' attorneys have a wide variety of tools to advertise their services and solicit new clients for litigation, including using judgments obtained in litigation against other pharmaceutical companies as an advertising tool. For these or other reasons, any significant product liability or mass tort litigation in which we are a defendant could have a larger number of plaintiffs than such actions have seen historically and we could also see an increase in number of cases filed against us because of the increasing use of widespread and media-varied advertising. Furthermore, a ruling against other pharmaceutical companies in product liability or mass tort litigation in which we are not a defendant could have a negative impact on pending litigation where we are a defendant.

In addition, in the case of products that do not meet approved specifications or for which subsequent data demonstrate such products may be unsafe, ineffective or misused, it may be necessary for us to initiate voluntary or mandatory recalls or withdraw such products from the market. Any such recall or withdrawal could result in adverse publicity, costs connected to the recall and loss of revenue. Adverse publicity could also result in an increased number of additional product liability claims, whether or not these claims have a basis in scientific fact. See the principal risk "Public concern around the abuse of opioids, including law enforcement concerns over diversion and marketing of opioids, and regulatory efforts to combat abuse, could result in costs to our business" for more information.

If we are found liable in any lawsuits, such as a product liability claim or series of claims, including those described above and below, or in connection with other legal proceedings, including those related to sales, marketing or pricing practices, government investigations, product recalls or the sale, marketing and/or distribution of prescription opioid medications, it could result in the imposition of damages, including punitive damages, substantial fines, significant reputational harm, civil lawsuits and criminal penalties, interruptions of business, modification of business practices, equitable remedies and other sanctions against us or our personnel as well as significant legal and other costs. We may also voluntarily settle cases even if we believe that we have meritorious defenses because of the significant legal and other costs that may be required to defend such actions. As a result, we may experience significant negative impacts on our operations. To satisfy judgments or settlements, we also may need to seek financing, which may not be available on terms acceptable to us, or at all, when required. Judgments also could cause defaults under our debt agreements and/or restrictions on our product use and we could incur losses as a result. Any of the risks above could materially and adversely impact our business, financial condition, results of operations, liquidity and cash flows.

Any such result may cause us to pursue one or more remedial measures, including internal reorganizations and/or other restructuring activities, strategic corporate alignment and cost-saving initiatives or other significant corporate transactions. See the principal risk "Our ability to fund our operations, maintain liquidity and meet our financing obligations is reliant on our operations, which are subject to significant risks and uncertainties" for more information. Likewise, any internal reorganizations and/or other restructuring activities, strategic corporate alignment and cost-saving initiatives or other significant corporate transactions may be complex, could entail significant cost and charges or could otherwise negatively impact shareholder value and there can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all.

We may not have and may be unable to obtain or maintain in the future product liability insurance on acceptable terms or with adequate coverage against potential liabilities or other losses, such as the cost of a recall, if any claim is brought against us, regardless of the success or failure of the claim. For example, we generally no longer have product liability insurance to cover the claims in connection with the mesh-related litigation described above. Additionally, we may be limited by the surviving insurance policies of our acquired subsidiaries, which may not be adequate to cover against potential liabilities or other losses. Even where claims are submitted to insurance carriers for defense and indemnity, there can be no assurance that the claims will be fully covered by insurance or that the indemnitors or insurers will remain financially viable. The failure to generate sufficient cash flow or to obtain other financing could affect our ability to pay the amounts due under those liabilities not covered by insurance.

See Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report for further discussion of the forgoing and other material legal proceedings.

Our ability to fund our operations, maintain liquidity and meet our financing obligations is reliant on our operations, which are subject to significant risks and uncertainties.

We rely on cash from operations as well as access to the financial markets to fund our operations, maintain liquidity and meet our financial obligations. Our operations are subject to many significant risks and uncertainties, such as the risks described in this "Principal Risks" section, several of which may be outside of our control. These risks and uncertainties include competition from, and legal challenge by, generic manufacturers, such as those challenging the validity and/or enforceability of our products or filing ANDAs seeking FDA approval of generic versions of certain of our key products, including VASOSTRICT®. See the principal risk "If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of our branded drugs, our sales may suffer" for more information. Additionally, we face significant risks and uncertainties relating to our outstanding and future legal proceedings and governmental investigations, including those related to our sale, marketing and/or distribution of prescription opioid medications. See the principal risk "We have been, continue to be and may be the subject of lawsuits, product liability claims, other significant legal proceedings, government investigations or product recalls for which we may be unable to obtain or maintain insurance adequate to cover potential liabilities" for more information. Any negative development or outcome in connection with any or all of these risks and uncertainties could result in significant consequences, including one or more of the following:

- causing a substantial portion of our cash flows from operations to be dedicated to the payment of legal or related expenses and therefore unavailable for other purposes, including the payment of principal and interest on our indebtedness, our operations, capital expenditures and future business opportunities;
- limiting our ability to incur additional borrowings under our existing facilities or to obtain additional debt or equity financing for working capital, capital expenditures, business development, debt service requirements, acquisitions or general corporate or other purposes, or to refinance our indebtedness;
- limiting our ability to adjust to changing market conditions, causing us to be more vulnerable to periods of negative or slow growth in the general economy or in our business, causing us to be unable to carry out capital spending that is important to our growth and placing us at a competitive disadvantage;
- limiting our ability to attract and retain key personnel;
- causing us to be unable to maintain compliance with or making it more difficult for us to satisfy our financial obligations under certain of our outstanding debt obligations, causing a downgrade of our debt and long-term corporate ratings and exposing us to potential events of default (if not cured or waived) under financial and operating covenants contained in our or our subsidiaries' outstanding indebtedness that could have a material adverse effect on our business, financial condition, results of operations, liquidity and cash flows.

If we are unable to fund our operations and liquidity needs, such as future capital expenditures and payment of our indebtedness, we may be required to refinance all or part of our then-existing indebtedness, sell assets, reduce or delay capital expenditures, seek to raise additional capital, pursue one or more internal reorganizations and/or other restructuring activities, strategic corporate alignment and cost-saving initiatives or other significant corporate transactions, any of which could have a material adverse effect on our operations and financial condition. Any refinancing of our substantial indebtedness could be at significantly higher interest rates, which will depend on the conditions of the markets and our financial condition at such time, and may require us to comply with more onerous covenants, which could further restrict our business operations. In addition, the terms of existing or future debt agreements may restrict us from adopting any of these alternatives. Likewise, any internal reorganizations and/or other restructuring activities, strategic corporate alignment and cost-saving initiatives or other significant corporate transactions may be complex, could entail significant costs and charges or could otherwise negatively impact shareholder value and there can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all. The failure to generate sufficient liquidity or to achieve any of these alternatives could materially adversely affect our business, financial condition and results of operations.

Our ability to protect and maintain our proprietary and licensed third party technology, which is vital to our business, is uncertain.

Our success, competitive position and future profit will depend in part on our ability to obtain and protect patent rights relating to our current and future technologies, processes and products. Our policy is to seek patent protection for technologies, processes and products we own and to enforce the intellectual property rights we own and license. The patent applications we submit and have submitted may not result in patents being issued. If an invention qualifies as a joint invention, the joint inventor may have intellectual property rights in the invention, which it might not protect. A third party may infringe upon, design around or develop uses not covered by any patent issued or licensed to us and our patents may not otherwise be commercially viable. In this regard, the patent position of pharmaceutical compounds and compositions is particularly uncertain. Even issued patents may later be modified or revoked by the PTO, by comparable foreign patent offices or by a court following legal proceedings. Laws relating to such rights may in the future also be changed or withdrawn. Upon the expiration or loss of necessary intellectual property protection for a product, others may manufacture and distribute such patented product, which will result in the loss of a significant portion of our sales of that product.

In addition, our success, particularly in our branded businesses, depends in part on the ability of our partners and suppliers to obtain, maintain and enforce patents and protect trademarks, trade secrets, know-how and other intellectual property and proprietary information. Our ability to commercialize any branded product successfully will largely depend upon our and/or our partners' or suppliers' ability to obtain and maintain patents and trademarks of sufficient scope to lawfully prevent third-parties from developing and/or marketing infringing products.

The degree of protection any patents will afford is uncertain, including whether the protection obtained will be of sufficient breadth and degree to protect our commercial interests in all the jurisdictions where we conduct business. The issuance of a patent is not conclusive as to its claim scope, validity or enforceability. These patent rights may be challenged, revoked, invalidated, infringed or circumvented by third parties. The patent positions of pharmaceutical companies, including us, are generally uncertain and involve complex legal and factual questions. There is no assurance that any of our patent claims in our pending non-provisional and provisional patent applications relating to our technologies, processes or products will be issued or, if issued, that any of our existing and future patent claims will be held valid and enforceable against third-party infringement. Moreover, any patent claims relating to our technologies, processes and products may not be sufficiently broad to protect our technologies, processes and products. Our patent claims may not afford us protection against competitors with similar technology. It is possible that we could incur significant costs and management distraction if we are required to initiate litigation against others to protect or enforce our intellectual property rights. Such patent disputes may be lengthy and a potential violator of our patents may bring a potentially infringing product to market during the dispute, subjecting us to competition and damages due to infringement of the competitor product. No assurance can be given that, if challenged, our patents would be declared by the PTO, comparable foreign patent offices or a court to be valid or enforceable or that, even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents.

Furthermore, our products may infringe on the patents or other intellectual property rights held by third parties. It is also possible that third parties will obtain patent or other proprietary rights that might be necessary or useful for the development, manufacture or sale of our products. If we infringe on the intellectual property rights of others, we could lose our right to develop, manufacture or sell products or we could be required to pay monetary damages or royalties to license proprietary rights from third parties and we may not be able to obtain such licenses on commercially reasonable terms or at all. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products.

The Group also relies on trade secrets and other unpatented proprietary information, which it generally seeks to protect by confidentiality and nondisclosure agreements with its employees, consultants, advisors and partners. These agreements may not effectively prevent disclosure of confidential information and may not provide the Group with an adequate remedy in the event of unauthorized disclosure. For example, in August 2017, we filed a complaint against QuVa Pharma, Inc. and certain individual defendants in the U.S. District Court for the District of New Jersey alleging misappropriation in violation of the federal Defend Trade Secrets Act, New Jersey's Trade Secrets Act and New Jersey common law, as well as unfair competition, breach of contract, breach of fiduciary duty, breach of the duty of loyalty, tortious interference with contractual relations and breach of the duty of confidence in connection with VASOSTRICT®, a vasopressin-based cardiopulmonary drug. For more information regarding this litigation, see Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report. Even if third parties misappropriate or infringe upon our proprietary rights, we may not be able to discover or determine the extent of any such unauthorized use and we may not be able to prevent third parties from misappropriating or infringing upon our proprietary rights. In addition, if the Group's employees, scientific consultants or partners develop inventions or processes that may be applicable to the Group's existing products or products under development, such inventions and processes will not necessarily become the Group's property and may remain the property of those persons or their employers.

If we are unable to adequately protect our technology, trade secrets or proprietary know-how, or enforce our intellectual property rights, our results of operations, financial condition and cash flows could be materially adversely affected.

Our competitors or other third parties may allege that we are infringing their intellectual property, forcing us to expend substantial resources in litigation, the outcome of which is uncertain. Any unfavorable outcome of such litigation, including losses related to "at-risk" product launches, could have a material adverse effect on our business, financial position and results of operations.

Companies that produce branded pharmaceutical products routinely bring litigation against ANDA or similar applicants that seek regulatory approval to manufacture and market generic forms of their branded products, alleging patent infringement or other violations of intellectual property rights. Patent holders may also bring patent infringement suits against companies that are currently marketing and selling approved generic products. Litigation often involves significant expense. Additionally, if the patents of others are held valid, enforceable and infringed by our current products or future product candidates, we would, unless we could obtain a license from the patent holder, need to delay selling our corresponding generic product and, if we are already selling our product, cease selling and potentially destroy existing product stock. Additionally, we could be required to pay monetary damages or royalties to license proprietary rights from third parties and we may not be able to obtain such licenses on commercially reasonable terms or at all.

There may be situations in which we may make business and legal judgments to market and sell products that are subject to claims of alleged patent infringement prior to final resolution of those claims by the courts based upon our belief that such patents are invalid, unenforceable or are not infringed by our marketing and sale of such products. This is commonly referred to in the pharmaceutical industry as an "at-risk" launch. The risk involved in an at-risk launch can be substantial because, if a patent holder ultimately prevails against us, the remedies available to such holder may include, among other things, damages calculated based on the profits lost by the patent holder, which can be significantly higher than the profits we make from selling the generic version of the product. Moreover, if a court determines that such infringement is willful, the damages could be subject to trebling. We could face substantial damages from adverse court decisions in such matters. We could also be at risk for the value of such stock that we are unable to market or sell.

Agreements between branded pharmaceutical companies and generic pharmaceutical companies are facing increased government scrutiny and private litigation in the U.S. and abroad.

We are involved in numerous patent litigations in which generic companies challenge the validity or enforceability of our products' listed patents and/or the applicability of these patents to the generic applicant's products. Likewise, we are also involved in patent litigations in which we challenge the validity or enforceability of innovator companies' listed patents and/or their applicability to our generic products. Therefore, settling patent litigations has been and is likely to continue to be part of our business. Parties to such settlement agreements in the U.S., including us, are required by law to file them with the U.S. Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ) for review. The FTC has publicly stated that, in its view, such settlement agreements may violate antitrust laws. In some instances, the FTC has brought actions against brand and generic companies that have entered into such agreements. Accordingly, we may receive formal or informal requests from the FTC for information about any such settlement agreement we enter into, and there is a risk that the FTC may commence an action against us alleging violation of the antitrust laws.

In addition, some members of the U.S. Congress have proposed legislation that would limit the types of settlement agreements generic manufacturers can enter into with brand companies. In 2013, the Supreme Court, in *FTC v. Actavis*, determined that reverse payment patent settlements between generic and brand companies should be evaluated under the rule of reason, but provided limited guidance beyond the selection of this standard. Because the Supreme Court did not articulate the full range of criteria upon which a determination of legality of such settlements would be based, or provide guidance on the precise circumstances under which such settlements would always qualify as legal, there may be extensive litigation over what constitutes a reasonable and lawful patent settlement between a brand and generic company. For example, certain of our subsidiaries are subject to multiple lawsuits purporting to be or certified as class actions brought by direct and indirect payers alleging that a settlement agreement with Impax Laboratories, LLC (Impax) regarding the OPANA® ER patent litigation was unlawful in violation of federal antitrust laws and various state laws.

We have significant goodwill and other intangible assets. Consequently, potential impairment of goodwill and other intangibles may significantly impact our profitability.

Goodwill and other intangibles represent a significant portion of our assets. As of December 31, 2018 and 2017, goodwill and other intangibles comprised approximately 71% and 75%, respectively, of our total assets. Goodwill and other indefinite-lived intangible assets are subject to impairment tests at least annually. Additionally, impairment tests must be performed for certain assets whenever events or changes in circumstances indicate such assets' carrying amounts may not be recoverable.

For the years ended December 31, 2018 and 2017, we recorded asset impairment charges of $0.9 billion and $1.2 billion, respectively, which related primarily to goodwill and other intangible assets. Refer to Note 9. Goodwill and Other Intangibles of the accompanying Consolidated Financial Statements included in this report for examples and a discussion of material impairment tests and impairment charges during the years ended years ended December 31, 2018 and 2017. The procedures and assumptions used in our goodwill and intangible assets impairment testing are discussed in in Note 9. Goodwill and Other Intangibles of the accompanying Consolidated Financial Statements included in this report.

Events giving rise to asset impairments are an inherent risk in the pharmaceutical industry and often cannot be predicted. As a result of the significance of goodwill and other intangible assets, our results of operations and financial position in a future period could be negatively impacted should additional impairments of our goodwill or other intangible assets occur.

We are subject to various regulations pertaining to the marketing of our products and services.

We are subject to various federal and state laws pertaining to healthcare fraud and abuse involving the marketing and pricing of our products and services, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration for the purchase of our products and services, including inducements to potential patients to request our products and services and inducements to healthcare professionals to prescribe and use our products. Additionally, product promotion, educational activities, support of continuing medical education programs and other interactions with healthcare professionals must be conducted in a manner consistent with FDA regulations and the Anti-Kickback Statute. The Anti-Kickback Statute, with certain exceptions or exemptions published by the Office of the Inspector General of the Department of Health and Human Services (HHS-OIG), prohibits persons or entities from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. Violations of the Anti-Kickback Statute also carry potential federal False Claims Act liability. Additionally, many states have adopted laws similar to the Anti-Kickback Statute, without identical exceptions or exemptions. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payer, not only the Medicare and Medicaid programs. Any such regulations or requirements may be difficult and expensive for us to comply with, may delay our introduction of new products, may adversely affect our total turnover and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

In February 2019, HHS-OIG issued a Proposed Rule: *Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees* to: (i) modify the definition of a discount eligible for safe harbor protection to exclude certain reductions in price or other remuneration, including payments that may be labeled as "rebates," from prescription pharmaceutical product manufacturers to Medicare Part D plan sponsors, Medicaid managed care organizations (MCOs) or pharmacy benefit managers (PBMs) under contract with either; (ii) adopt a new safe harbor that would protect certain point-of-sale price reductions offered by manufacturers on certain prescription pharmaceutical products payable under Medicare Part D or by Medicaid MCOs and (iii) adopt a new safe harbor that would protect fixed fees that manufacturers pay to PBMs for services rendered to manufacturers that meet specified criteria. It is unclear at this time whether this Proposed Rule will be adopted or, if adopted, what effect, if any, it would have on the cost and ability to comply with the federal Anti-Kickback Statute or on our business, including our ongoing relationships with contracting partners in the drug distribution supply chain.

Sanctions for violating these laws include criminal penalties and civil sanctions and possible exclusion from federally funded healthcare programs such as Medicare and Medicaid as well as potential liability under the False Claims Act and applicable state false claims acts. There can be no assurance that our practices will not be challenged under these laws in the future, that changes in these laws or interpretation of these laws would not give rise to new challenges of our practices or that any such challenge would not have a material adverse effect on our business or results of operations. Law enforcement agencies sometimes initiate investigations into sales, marketing and/or pricing practices based on preliminary information or evidence, and such investigations can be and often are closed without any enforcement action. Nevertheless, these types of investigations and any related litigation can result in: (i) large expenditures of cash for legal fees, payment of penalties and compliance activities; (ii) limitations on operations; (iii) diversion of management resources; (iv) injury to our reputation and (v) decreased demand for our products.

In addition, our company is subject to statutory and regulatory restrictions on the promotion of uses of prescription drugs or devices that are not cleared or approved by the FDA, which are commonly referred to in the pharmaceutical industry as "off-label" uses. Although the FDA does not regulate a physician's choice of medications, treatments or product uses, the FFDCA and FDA regulations and guidance restrict the ability of healthcare companies to communicate with patients, physicians and other third-parties about off-label uses. Prohibitions on the promotion of off-label uses and against promotional practices deemed false or misleading are actively enforced by various parties at both the federal and state level. A company that is found to have improperly promoted its products under these laws may be subject to significant liability, including significant administrative, civil and criminal sanctions including, but not limited to, significant civil damages, criminal fines and exclusion from participation in Medicare, Medicaid and other federal healthcare programs. Applicable laws governing product promotion also provide for administrative, civil and criminal liability for individuals, including, in some circumstances, potential strict vicarious liability. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers or other persons allegedly harmed by such conduct.

We have established and implemented a corporate compliance program designed to prevent, detect and correct violations of state and federal healthcare laws, including laws related to advertising and promotion of our products. Nonetheless, enforcement agencies or private plaintiffs may take the position that we are not in compliance with such requirements and, if such non-compliance is proven, the Group and, in some cases, individual employees, may be subject to significant liability, including the aforementioned administrative, civil and criminal sanctions.

Furthermore, in February 2014, Endo Pharmaceuticals Inc. (EPI) entered into a Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services to resolve allegations regarding the promotion of LIDODERM®. In March 2013, our subsidiary, Par Pharmaceutical Companies, Inc., entered into a CIA and a Plea Agreement with the DOJ to resolve allegations regarding the promotion of MEGACE® ES. Those agreements place certain obligations on us related to the marketing of our pharmaceutical products and our healthcare regulatory compliance program, including reporting requirements to the U.S. government, detailed requirements for our compliance program, code of conduct and policies and procedures and the requirement to engage an Independent Review Organization. We have implemented procedures and practices to comply with the CIA, including the engagement of an Independent Review Organization. In the event we breach the Plea Agreement and/or the CIAs, there is a risk the government would seek remedies provided for in those agreements, including instituting criminal prosecution against us, seeking to impose stipulated penalties or seeking to exclude us from participation in federal healthcare programs.

The pharmaceutical industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business.

Governmental authorities such as the FDA impose substantial requirements on the development, manufacture, holding, labeling, marketing, advertising, promotion, distribution and sale of therapeutic pharmaceutical products through lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures. In addition, before obtaining regulatory approvals for certain generic products, we must conduct limited bioequivalence studies and other research to show comparability to the branded products. A failure to obtain satisfactory results in required pre-marketing trials may prevent us from obtaining required regulatory approvals. The FDA may also require companies to conduct post-approval studies and post-approval surveillance regarding their drug products and to report adverse events.

Before obtaining regulatory approvals for the sale of any new product candidate, we must demonstrate through preclinical studies and clinical trials that such product candidate is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product candidate. Likewise, we may not be able to demonstrate through clinical trials that a product candidate's therapeutic benefits outweigh its risks. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals. Clinical trials can be delayed for reasons outside of our control, which can lead to increased development costs and delays in regulatory approval. For example, there is substantial competition to enroll patients in clinical trials, and such competition has delayed clinical development of our products in the past. For example, patients may not enroll in clinical trials at the rate expected or patients may drop out after enrolling in the trials or during the trials. In addition, we rely on collaboration partners that may control or make changes in trial protocol and design enhancements, or encounter clinical trial compliance-related issues, which may also delay clinical trials. Product supplies may be delayed or be insufficient to treat the patients participating in the clinical trials, or manufacturers or suppliers may not meet the requirements of the FDA or foreign regulatory authorities, such as those relating to cGMP. We also may experience delays in obtaining, or we may not obtain, required initial and continuing approval of our clinical trials from institutional review boards. We may experience delays or undesired results in these or any other of our clinical trials.

The FDA and/or foreign regulatory agencies may not approve, clear for marketing or certify any products developed by us. Any approval by regulatory agencies may subject the marketing of our products to certain limits on indicated use. The FDA or foreign regulatory authorities may not agree with our assessment of the clinical data or they may interpret it differently. Such regulatory authorities may require additional or expanded clinical trials. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals or clearances of products developed by us would adversely affect the marketing of these products and our ability to generate product turnover, which would adversely affect our financial condition and results of operations.

In addition, specifically with respect to pharmaceutical products, the submission of an NDA, ANDA, BLA or supplemental Biologics License Application (sBLA) to the FDA with supporting clinical safety and efficacy data, for example, does not guarantee that the FDA will grant approval to market the product. Meeting the FDA's regulatory requirements to obtain approval to market a drug product, which varies substantially based on the type, complexity and novelty of the pharmaceutical product, typically takes years, if approved at all, and is subject to uncertainty. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we may request, may grant approval contingent on conditions such as the performance and results of costly post-marketing clinical trials or REMS or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, or reimbursement by government payers or other payers may not be approved at the price we intend to charge for our products. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. Although the FDA is not required to follow the recommendations of its Advisory Committees, it usually does. A negative Advisory Committee meeting could signal a lower likelihood of approval, although the FDA may still end up approving our application. Regardless of an Advisory Committee meeting outcome or the FDA's final approval decision, public presentation of our data may shed positive or negative light on our application.

With respect to our Supplemental New Drug Application for OPANA® ER, the FDA scheduled a Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee in March 2017 to discuss pre- and post-marketing data about the abuse of OPANA® ER and the overall risk-benefit of this product. The Advisory Committees were also scheduled to discuss abuse of generic oxymorphone ER and oxymorphone immediate-release products. In March 2017, the Advisory Committees voted 18 to eight, with one abstention, that the benefits of reformulated OPANA® ER no longer outweigh its risks. While several of the Advisory Committee members acknowledged the role of OPANA® ER in clinical practice, others believed its benefits were overshadowed by the continuing public health concerns around the product's misuse, abuse and diversion. In June 2017, the FDA requested that we voluntarily withdraw OPANA® ER from the market and, in July 2017, after careful consideration and consultation with the FDA, we decided to voluntarily remove OPANA® ER from the market to the Group's financial detriment. During the second quarter of 2017, we began to work with the FDA to coordinate an orderly withdrawal of the product from the market. By September 1, 2017, we ceased shipments of OPANA® ER to customers and we expect the NDA will be withdrawn. These actions had an adverse effect on our turnover and, as a result of these actions, we have incurred and expect to incur certain charges. Actions similar to these, such as recalls or withdrawals, could divert management time and attention, reduce market acceptance of all of our products, harm our reputation, reduce our turnover, lead to additional charges or expenses or result in product liability claims, any of which could have a material adverse effect on our results of operations and financial condition.

Some drugs are available in the U.S. that are not the subject of an FDA-approved NDA. In 2011, the FDA's Center for Drug Evaluation and Research (CDER) Office of Compliance modified its enforcement policy with regard to the marketing of such "unapproved" marketed drugs. Under CDER's revised guidance, the FDA encourages manufacturers to obtain NDA approvals for such drugs by requiring unapproved versions to be removed from the market after an approved version has been introduced, subject to a grace period at the FDA's discretion. This grace period is intended to allow an orderly transition of supply to the market and to mitigate any potential related drug shortage. Depending on the length of the grace period and the time it takes for subsequent applications to be approved, this may result in a period of de facto market exclusivity to the first manufacturer that has obtained an approved NDA for the previously unapproved marketed drug. We may seek FDA approval for certain unapproved marketed drug products through the 505(b)(2) regulatory pathway. Even if we receive approval for an NDA under section 505(b)(2) of the FFDCA, the FDA may not take timely enforcement action against companies marketing unapproved versions of the drug; therefore, we cannot be sure that that we will receive the benefit of any de facto exclusive marketing period or that we will fully recoup the expenses incurred to obtain an approval. In addition, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, this could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

The ANDA approval process for a new product varies in time, generally requiring a minimum of 10 months following submission of the ANDA to FDA, but could also take several years from the date of application. The timing for the ANDA approval process for generic products is difficult to estimate and can vary significantly. ANDA approvals, if granted, may not include all uses (known as indications) for which a company may seek to market a product.

Further, once a product is approved or cleared for marketing, failure to comply with applicable regulatory requirements can result in, among other things, suspensions or withdrawals of approvals or clearances; seizures or recalls of products; injunctions against the manufacture, holding, distribution, marketing and sale of a product; and civil and criminal sanctions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals or clearances. Meeting regulatory requirements and evolving government standards may delay marketing of our new products for a considerable period of time, impose costly procedures upon our activities and result in a competitive advantage to larger companies that compete against us.

Based on scientific developments, post-market experience or other legislative or regulatory changes, the current FDA standards of review for approving new pharmaceutical products, or new indications or uses for approved or cleared products, are sometimes more stringent than those that were applied in the past.

Some new or evolving FDA review standards or conditions for approval or clearance were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have safety databases on these products that are as extensive as some products developed more recently. Accordingly, we believe the FDA has expressed an intention to develop such databases for certain of these products, including many opioids. In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which, based on certain structural characteristics and laboratory tests, may indicate the potential for having mutagenic effects. The FDA has required, and may continue to require, more stringent controls of the levels of these impurities in drug products for approval.

Also, the FDA may require labeling revisions, formulation or manufacturing changes and/or product modifications for new or existing products containing such impurities. The FDA's more stringent requirements, together with any additional testing or remedial measures that may be necessary, could result in increased costs for, or delays in, obtaining approval for certain of our products. Although we do not believe that the FDA would seek to remove a currently marketed product from the market unless such mutagenic effects are believed to indicate a significant risk to patient health, we cannot make any such assurance.

In May of 2016, an FDA advisory panel recommended mandatory training of all physicians who prescribe opioids on the risks of prescription opioids. In 2016, the CDC also issued a guideline for prescribing opioids for chronic pain that provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care and end-of-life care. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, these or any new regulations or requirements may be difficult and expensive for us to comply with, may delay our introduction of new products, may adversely affect our total turnover and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

The FDA has the authority to require companies to undertake additional post-approval studies to assess known or signaled safety risks, to make any labeling changes to address those risks and to formulate approved REMS to confirm a drug's benefits outweigh its risks. For example, in 2015, the FDA sent letters to a number of manufactures, including Endo, requiring that a randomized, double-blind, placebo-controlled clinical trial be conducted to evaluate the effect of testosterone replacement therapy on the incidence of major adverse cardiovascular events in men. The letter received by Endo required that we include new safety information in the labeling and Medication Guide for certain prescription medications containing testosterone, such as TESTIM®.

The FDA's exercise of its authority under the FFDCA could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable requirements and costs. Post-marketing studies and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our products. Furthermore, the discovery of significant safety or efficacy concerns or problems with a product in the same therapeutic class as one of our products that implicate or appear to implicate the entire class of products could have an adverse effect on sales of our product or, in some cases, result in product withdrawals. The FDA has continuing authority over the approval of an NDA or ANDA and may withdraw approval if, among other reasons, post-marketing clinical or other experience, tests or data show that a drug is unsafe for use under the conditions upon which it was approved, or if FDA determines that there is a lack of substantial evidence of the drug's efficacy under the conditions described in its labeling. Furthermore, new data and information, including information about product misuse or abuse at the user level, may lead government agencies, professional societies, practice management groups or patient or trade organizations to recommend or publish guidance or guidelines related to the use of our products, which may lead to reduced sales of our products.

The FDA and the DEA have important and complementary responsibilities with respect to our business. The FDA administers an application and post-approval monitoring process to confirm that products that are available in the market are safe, effective and consistently of uniform, high quality. The DEA administers registration, drug allotment and accountability systems to satisfy against loss and diversion of controlled substances. Both agencies have trained investigators that routinely, or for cause, conduct inspections, and both have authority to seek to enforce their statutory authority and regulations through administrative remedies as well as civil and criminal enforcement actions.

The FDA regulates and monitors the quality of drug clinical trials to provide human subject protection and to support marketing applications. The FDA may place a hold on a clinical trial and may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. The FDA also regulates the facilities, processes and procedures used to manufacture and market pharmaceutical products in the U.S. Manufacturing facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with the latest cGMP regulations, which are enforced by the FDA. Compliance with clinical trial requirements and cGMP regulations requires significant expenditures and the dedication of substantial resources. In the event an approved manufacturing facility for a particular drug is required by the FDA to curtail or cease operations, or otherwise becomes inoperable, or a third party contract manufacturing facility faces manufacturing problems, obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could result in production delays, which could adversely affect our business, results of operations, financial condition and cash flows.

The FDA is authorized to perform inspections of U.S. and foreign facilities under the FFDCA. At the end of such an inspection, the FDA could issue a Form 483 Notice of Inspectional Observations, which could cause us to modify certain activities identified during the inspection. Following such inspections, the FDA may issue an untitled letter as an initial correspondence that cites violations that do not meet the threshold of regulatory significance for a Warning Letter. FDA guidelines also provide for the issuance of Warning Letters for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. The FDA also may issue Warning Letters and untitled letters in connection with events or circumstances unrelated to an FDA inspection.

Similar to other healthcare companies, our facilities in multiple countries across the full range of our business units are subject to routine and new-product related inspections by regulatory authorities including the FDA, the Medicines and Healthcare products Regulatory Agency, the Health Products Regulatory Authority and Health Canada. In the past, some of these inspections have resulted in inspection observations (including FDA Form 483 observations). We have responded to all inspection observations within the required timeframe and have implemented, or are continuing to implement, the corrective action plans as agreed with the relevant regulatory agencies.

Several of our core products contain controlled substances. The stringent DEA regulations on our use of controlled substances include restrictions on their use in research, manufacture, distribution and storage. A breach of these regulations could result in imposition of civil penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances. In addition, failure to comply with applicable legal requirements subjects the manufacturing facilities of our subsidiaries and manufacturing partners to possible legal or regulatory action, including shutdown. Any such shutdown may adversely affect their ability to supply us with product and thus, our ability to market affected products. This could have a negative impact on our business, results of operations, financial condition, cash flows and competitive position. See also the principal risk described under the caption "The DEA limits the availability of the active ingredients used in many of our products as well as the production of these products, and, as a result, our procurement and production quotas may not be sufficient to meet commercial demand or complete clinical trials."

In addition, we are subject to the Federal Drug Supply Chain Security Act (DSCSA) enacted by the U.S. government, which 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. Compliance with DSCSA and future U.S. federal or state electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens.

We cannot determine what effect changes in regulations or legal interpretations or requirements by the FDA, the courts or others, when and if promulgated or issued, or advisory committee meetings may have on our business in the future. Changes could, among other things, require different labeling, monitoring of patients, interaction with physicians, education programs for patients or physicians, curtailment of necessary supplies or limitations on product distribution. Any such changes could result in additional litigation and may have an adverse effect on our business, results of operations, financial condition and cash flows. The evolving and complex nature of regulatory science and regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that, from time to time, we will be adversely affected by regulatory actions despite our ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

The success of our acquisition and licensing strategy is subject to uncertainty and any completed acquisitions or licenses may reduce our earnings, be difficult to integrate, not perform as expected or require us to obtain additional financing.

We regularly evaluate selective acquisitions and look to continue to enhance our product line by acquiring rights to additional products and compounds. Such acquisitions may be carried out through corporate acquisitions, asset acquisitions, licensing and joint venture arrangements or by acquiring other companies. However, we may not be able to complete acquisitions that meet our target criteria on satisfactory terms, if at all. In particular, we may not be able to identify suitable acquisition candidates. In addition, any acquisition of assets and rights to products and compounds may fail to accomplish our strategic objective and may not perform as expected. Further, if we are unable to maintain, on commercially reasonable terms, product, compound or other licenses that we have acquired, our ability to develop or commercialize our products may be inhibited. In order to continue to develop and broaden our product range, we must compete to acquire assets. Our competitors may have greater resources than us and therefore be better able to complete acquisitions, which could cause us to be unable to consummate acquisitions or cause the ultimate price we pay for acquisitions to increase. If we fail to achieve our acquisition goals, our growth may be limited.

In addition to the risks related to acquisition of assets and products, acquisitions of companies may expose us to additional risks, which may be beyond our control and may have a material adverse effect on our profitability and cash flows. The combination of two independent businesses is a complex, costly and time-consuming process. As a result, we may be required to devote significant management attention and resources to the integration of an acquired business into our practices and operations. Any integration process may be disruptive and, if implemented ineffectively, may restrict the realization of the full expected benefits.

In addition, any acquisitions we make may result in material unanticipated problems, expenses, liabilities, competitive responses and loss or disruption of relationships with customers, suppliers, partners, regulators and others with whom we have business or other dealings. The difficulties of combining operations of companies include, among others:

- diversion of management's attention to integration matters;
- difficulties in achieving anticipated cost or tax savings, synergies, business opportunities and growth prospects from the combination of the businesses;
- difficulties in the integration of operations and systems;
- the impact of pre-existing legal and/or regulatory issues;
- difficulties in conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the companies;
- difficulties in the assimilation of employees and retention of key personnel;
- difficulties in managing the expanded operations of a significantly larger and more complex company;
- challenges in retaining existing customers and obtaining new customers;
- potential unknown liabilities or larger liabilities than projected, adverse consequences and unforeseen increased expenses associated with the merger; and
- difficulties in coordinating a geographically dispersed organization.

The benefits of a merger are also subject to a variety of other factors, many of which are beyond our ability to control, such as changes in the rate of economic growth in jurisdictions in which the combined company will do business, the financial performance of the combined business in various jurisdictions, currency exchange rate fluctuations and significant changes in trade, monetary or fiscal policies, including changes in interest rates and tax law of the jurisdictions in which the combined company will do business. The impact of these factors, individually and in the aggregate, is difficult to predict, in part because the occurrence of the events or circumstances described in such factors may be interrelated, and the impact to the combined company of the occurrence of any one of these events or circumstances could be compounded or, alternatively, reduced, offset or more than offset by the occurrence of one or more of the other events or circumstances described in such factors.

In addition, based on current acquisition prices in the pharmaceutical industry, acquisitions could decrease our net profit per share and add significant intangible assets and related amortization or impairment charges. Our acquisition strategy may require us to obtain additional debt or equity financing, resulting in additional debt obligations, increased interest expense or dilution of equity ownership. We may not be able to finance acquisitions on terms satisfactory to us, or at all.

We may decide to sell assets, which could adversely affect our prospects and opportunities for growth.

We may from time to time consider selling certain assets if we determine that such assets are not critical to our strategy or we believe the opportunity to monetize the asset is attractive or for various other reasons, including for the reduction of indebtedness. For example, we divested both Litha and Somar in 2017 and various ANDAs throughout 2018. We will continue to explore the sale of certain non-core assets. Although our expectation is to engage in asset sales only if they advance or otherwise support our overall strategy, any such sale could reduce the size or scope of our business, our market share in particular markets or our opportunities with respect to certain markets, products or therapeutic categories. As a result, any such sale could have an adverse effect on our business, prospects and opportunities for growth, results of operations, financial condition and cash flows.

Our growth and development will depend on developing, commercializing and marketing new products, including both our own products and those developed with our collaboration partners. If we do not do so successfully, our growth and development will be impaired.

Our future turnover and profitability will depend, to a significant extent, upon our ability to successfully commercialize new branded and generic pharmaceutical products protected by patent or statutory authority in a timely manner. As a result, we must continually develop, test and manufacture new products, which must meet regulatory standards to receive requisite marketing authorizations. The process of developing and obtaining regulatory approvals for new products is time-consuming, costly and inherently unpredictable. Products we are currently developing may not receive the regulatory approvals or clearances necessary for us to market them and, if approved, we may be unable to successfully commercialize them on a timely basis or at all.

The successful commercialization of a product is subject to a number of factors, including:

- the timely filing of any NDA, ANDA, BLA, sBLA or other regulatory submission applicable to our product candidates, any adverse development or perceived adverse development with respect to the applicable regulatory agency's review of such regulatory submission and approval for the indication sought;
- the effectiveness, ease of use and safety of our products as compared to existing products;
- customer demand and the willingness of physicians and customers to adopt our products over products with which they may have more loyalty or familiarity and overcoming any biases towards our products;
- the cost of our product compared to alternative products and the pricing and commercialization strategies of our competitors;
- the success of our launch and marketing efforts;
- adverse publicity about us, our products, our competitors and their products or the industry as a whole or favorable publicity about competitors;
- the advent of new and innovative alternative products; and
- any unforeseen issues or adverse developments in connection with a product and any resulting litigation or regulatory scrutiny and harm to our reputation.

In addition, many risks associated with developing, commercializing and marketing new products are beyond our control. For example, some of our collaboration partners may decide to make substantial changes to a product's formulation or design, may experience financial difficulties or may have limited financial resources. Any of the foregoing may delay the development, commercialization and/or marketing of new products. In addition, if a co-developer on a new product terminates our collaboration agreement or does not perform under the agreement, we may experience delays and additional costs in developing and marketing that product.

We conduct research and development to enable us to manufacture and market pharmaceutical products in accordance with specific government regulations. Much of our drug development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. Typically, expenses related to research, development and regulatory approval of compounds for our branded pharmaceutical products are significantly greater than those expenses associated with generic products. Should we expand our research and development efforts, our research expenses will likely increase. Because of the inherent risk associated with research and development efforts in the healthcare industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful regulatory approval and introduction of new pharmaceutical products and failure in the development of any new product can occur at any point in the process, including late in the process after substantial investment. Also, after we submit a regulatory application, the relevant governmental health authority may require that we conduct additional studies, including, for example, studies to assess the product's interaction with alcohol. As a result, we may be unable to reasonably predict the total research and development costs to develop a particular product and there is a significant risk that the funds we invest in research and development will not generate financial returns. In addition, our operating results and financial condition may fluctuate as the amount we spend to research and develop, commercialize, acquire or license new products, technologies and businesses changes.

The availability of third party reimbursement for our products is uncertain, and thus we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third party reimbursement is not adequately provided.

Our ability to commercialize our products depends, in part, on the extent to which reimbursement for the costs of these products is available from government healthcare programs, such as Medicaid and Medicare, private health insurers and others. We cannot be certain that, over time, third party reimbursements for our products will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. Government payers, private insurers and other third party payers are increasingly attempting to contain healthcare costs by: (i) limiting both coverage and the level of reimbursement (including adjusting co-pays) for drugs, (ii) refusing, in some cases, to provide any coverage for off-label uses for drugs and (iii) requiring or encouraging, through more favorable reimbursement levels or otherwise, the substitution of generic alternatives to branded drugs. The Trump Administration also has been targeting drug prices in ways that could affect reimbursement for our products. For example, beginning in January 2019, Medicare Advantage Plans will be permitted to apply "step therapy" to products covered under Part B, which could impact our ability to negotiate for favorable product access in this sector. Additionally, in October 2018, President Trump announced a new initiative to contain drug costs by establishing an "international pricing index" that would be used as a benchmark in deciding how much to pay for Medicare Part B drugs. The Centers for Medicare and Medicaid Services (CMS) issued an Advance Notice of Proposed Rulemaking for the Medicare Program that would reduce Part B drug spending and reimbursement in part based on the prices that manufacturers charge to customers in foreign countries (also referred to as reference pricing). This proposal targets physician-administered drugs, and it is therefore possible that any final rule could adversely affect reimbursement for certain products that we sell, and we cannot anticipate the adverse impact of this or similar developments on our business. Additionally, the new Congress is considering multiple proposals impacting healthcare. There can be no assurance as to which proposals, if any, will be adopted, the final terms of any such proposals and the ultimate impact that such proposals would have on our business, results of operations, financial condition and cash flows.

New tariffs and evolving trade policy between the United States and other countries, including China, may have an adverse effect on our business and results of operations.

We conduct business globally and our operations, including third party suppliers, span numerous countries outside the U.S. There is currently significant uncertainty about the future relationship between the U.S. and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. The Trump Administration has called for substantial changes to U.S. foreign trade policy, including the possibility of imposing greater restrictions on international trade and significant increases in tariffs on goods imported into the U.S. In September 2018, the U.S. Trade Representative (USTR) enacted a tariff on the import of certain Chinese products with a combined import value of approximately $200 billion, including non-U.S. sourced APIs and starting materials used in our products. The tariff became effective on September 24, 2018, with an initial rate of 10%, and the Trump Administration has expressed a willingness to potentially increase tariffs to 25%. These tariffs could potentially disrupt our existing supply chains and impose additional costs on our business, including costs with respect to raw materials upon which our business depends. Furthermore, if tariffs, trade restrictions or trade barriers are placed on products such as ours by foreign governments, especially China, it could cause us to raise prices for our products, which may result in the loss of customers and our business, financial condition and results of operations may be harmed. If we are unable to pass along increased costs to our customers, our margins could be adversely affected. Additionally, it is possible further tariffs may be imposed that could affect imports of APIs and starting materials used in our products, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to APIs or starting materials used in our products, causing us to raise prices or make changes to our products, which could materially harm our business, financial condition and results of operations. Further, the continued threats of tariffs, trade restrictions and trade barriers could have a generally disruptive impact on the global economy and, therefore, negatively impact our sales. Given the unpredictable regulatory environment in China and the U.S. and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, regulatory changes or other retaliatory trade measures in the future could occur and could directly and adversely impact our business and results of operations.

We may experience pricing pressure on our products due to social or political pressure to lower the cost of drugs, which would reduce our turnover and future profitability.

We may experience downward pricing pressure on our products due to social or political pressure to lower the cost of drugs, which would reduce our turnover and future profitability. Price increases have resulted in increased public and governmental scrutiny of the cost of drugs. For example, U.S. federal prosecutors have issued subpoenas to pharmaceutical companies seeking information about pricing practices in connection with an investigation into pricing practices conducted by the U.S. Department of Justice. Several state attorneys general also have commenced drug pricing investigations and filed lawsuits against pharmaceutical companies, including Par Pharmaceutical, Inc., and the U.S. Senate has publicly investigated a number of pharmaceutical companies relating to price increases and pricing practices. Our turnover and future profitability could be negatively affected if these or other inquiries were to result in legislative or regulatory proposals limiting our ability to increase the prices of our products.

In addition, the Trump Administration and a number of federal legislators continue to scrutinize drug prices and are seeking ways to lower prices. For example, the Trump Administration's "Blueprint" on drug prices describes a number of mechanisms for lowering manufacturer list prices and reducing patient out-of-pocket costs. Although the Blueprint contains a number of policy objectives, we cannot know the form that any new requirements will take or the effect that they may have on our business. In addition, Congress has held a number of hearings related to drug prices and a bipartisan group of U.S. Senators introduced legislation that would require pharmaceutical manufacturers to justify certain price increases. A large number of individual states also have introduced legislation aimed at drug pricing regulation, transparency or both. For example, California, Oregon, Vermont and Nevada have enacted such laws. Our turnover and future profitability could be negatively affected by the passage of these laws or similar federal or state legislation. Pressure from social activist groups and future government regulations may also put downward pressure on the price of drugs in the future.

Our business is highly dependent upon market perceptions of us, our brands, and the safety and quality of our products, and may be adversely impacted by negative publicity or findings.

Market perceptions of us are very important to our business, especially market perceptions of our company and brands and the safety and quality of our products. If we, our partners and suppliers, or our brands suffer from negative publicity, or if any of our products or similar products which other companies distribute are subject to market withdrawal or recall or are proven to be, or are claimed to be, ineffective or harmful to consumers, our business, results of operations, financial condition and cash flows could be materially adversely affected.

For example, the pharmaceutical drug supply has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the internet. Third parties may illegally distribute and sell counterfeit versions of our products that do not meet the rigorous manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of API or no API at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

In addition, negative posts or comments about us on any social networking website could seriously damage our reputation. The inappropriate use of certain social media vehicles could cause brand damage or information leakage or could lead to legal implications from the improper collection and/or dissemination of personally identifiable information or the improper dissemination of material non-public information.

Furthermore, unfavorable media coverage of opioid pharmaceuticals could negatively affect our business, financial condition and results of operations. In recent years, opioid drug abuse has received a high degree of media coverage. Unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs, the limitations of abuse-deterrent forms, public inquiries and investigations into prescription drug abuse, litigation or regulatory activity could adversely affect our reputation. Such negative publicity could have an adverse effect on the potential size of the market for our drug candidates and decrease turnover and royalties, which would adversely affect our business and financial status. Additionally, such increased scrutiny of opioids generally, whether focused on our products or otherwise, could negatively impact our relationship with healthcare providers and other members of the healthcare community.

We are dependent on market perceptions, and negative publicity associated with product quality, patient illness or other adverse effects resulting from, or perceived to be resulting from, our products, or our partners' and suppliers' manufacturing facilities, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Our business and financial condition may be adversely affected by legislation.

In April 2018, New York enacted a statute called the Opioid Stewardship Act (the Stewardship Act), which, among other things, provided for certain sellers and distributors of certain opioids in the state of New York (the Contributing Parties) to make payments to a newly created Opioid Stewardship Fund (the Fund). By its terms, the Stewardship Act required Contributing Parties to pay a total of up to $100 million annually into the Fund, with each Contributing Party's share based on the total amount of morphine milligram equivalents of certain opioids sold or distributed by the Contributing Party in the state of New York during the preceding calendar year, subject to potential adjustments by the New York State Department of Health. Failure of a Contributing Party to make required reports or pay its ratable share, or a Contributing Party passing on the cost of its ratable share to a purchaser, could subject the Contributing Party to penalties. In December 2018, the U.S. District Court for the Southern District of New York held the Stewardship Act unconstitutional. This ruling is on appeal. If the decision is reversed, we may be deemed to be a Contributing Party under the Stewardship Act and even if we are not considered to be a Contributing Party, or such a determination is never made, other entities may attempt to seek reimbursement from Endo for payments made related to products manufactured by Endo and distributed in New York. Furthermore, the application of the Stewardship Act may require additional regulatory guidance, which could be substantially delayed, increasing the uncertainty as to the ultimate effect of the Stewardship Act on us. If we are ultimately deemed to be a Contributing Party under the Stewardship Act, or similar legislation that could be enacted by New York or other jurisdictions, compliance with those laws could have an adverse effect on our business, results of operations, financial condition and cash flows.

Additionally, in October 2018, the U.S. Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (H.R. 6). Intended to achieve sweeping reform to combat the opioid epidemic, H.R. 6, among other provisions, amends related laws administered by the FDA, DEA and CMS. Among other things, the law: amends requirements related to the FDA's authority to include packaging requirements in REMS requirements; increases civil and criminal penalties for drug manufacturers and distributors for failing to maintain effective controls against diversion of opioids or for failing to report suspicious opioid orders; requires the DEA to estimate the amount of opioid diversion when establishing manufacturing and procurement quotas; implements expanded anti-kickback and financial disclosure provisions; and authorizes the Department of Health and Human Services to implement a demonstration program which would award grants to hospitals and emergency departments to develop, implement, enhance or study alternative pain management protocols and treatments that limit the use and prescription of opioids in emergency departments. While the effect of this legislation is still uncertain, it is likely that our products will be affected by enforcement of the legislation, including through related policies and implementing regulations. It is possible that these changes in law could have an adverse effect on our business, results of operations, financial condition and cash flow.

Also in October 2018, the Canadian province of British Columbia enacted a statute called the Opioid Damages and Health Care Costs Recovery Act, which allows the British Columbia government to file a direct action against opioid manufacturers and wholesalers to recover the health care costs it has incurred, and will incur, resulting from an "opioid-related wrong." The statute defines "opioid-related wrong" to include any breach of a common law, equitable or statutory duty or obligation owed to persons in British Columbia who have been or might be exposed to an opioid product. The statute, among other effects, erases limitation periods, reverses certain burdens of proof as to causation, allows the use of population-based evidence and restricts discovery of some relevant documents. It is possible that this statute, or similar statutes enacted by other jurisdictions, and resultant litigation, could have an adverse effect on our business, results of operations, financial condition and cash flows.

In Canada, the prices of patented drug products are subject to regulation by the Patented Medicine Prices Review Board (PMPRB). Under the Canadian Patent Act and Patented Medicines Regulations, patentees of inventions that pertain to drug products sold in Canada are periodically required to file price and sales information about their patented drug products with the PMPRB. The PMPRB reviews this information on an ongoing basis to ensure that the prices charged by pharmaceutical companies for patented drugs are not excessive and comply with the pricing guidelines established by the PMPRB. There is risk that we could fail to comply with the PMPRB's current guidelines, such as upon the launch of a new product in Canada for which the PMPRB has not yet assessed pricing, or that the guidelines could change such that the current price of our drug products will be considered excessive under the updated guidelines. The Canadian government has published proposed amendments to the Patented Medicines Regulations and, if these amendments are passed and come into force, the PMPRB guidelines will be updated to account for new price regulatory factors. Failure by us to comply with the current or future guidelines could ultimately result in us reducing the prices of the drug products we sell in Canada and/or making a payment to the Canadian government to offset turnover deemed by the PMPRB to be excessive, which could ultimately reduce the turnover and cash flows of our International Pharmaceuticals segment and could have an adverse effect on our business, results of operations, financial condition, cash flow and reputation.

Public concern around the abuse of opioids, including law enforcement concerns over diversion and marketing of opioids, and regulatory efforts to combat abuse, could result in costs to our business.

Media stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are commonplace. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of opioid drugs; the limitations of abuse-deterrent formulations; the ability of drug abusers to discover previously unknown ways to abuse our products; public inquiries and investigations into prescription drug abuse; litigation or regulatory activity regarding sales, marketing, distribution or storage of opioids could have a material adverse effect on our reputation and impact on the results of litigation.

Manufacturers of prescription opioid medications have been the subject of significant civil and criminal investigatory and enforcement action even in cases where such medications have received approval from the FDA or similar regulatory authorities. In addition, numerous governmental and private persons and entities are pursuing civil litigation against opioid manufacturers and distributors, invoking current laws and regulations relating to opioids and/or other prescription medicines, as well as novel uses of other laws that seek to hold accountable opioid manufacturers for opioid misuse. See Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report for more information.

Regulatory actions at the federal, state and local level may seek to limit or restrict the manufacturing, distribution or sale of opioids, both directly and indirectly, and/or to impose novel policy or regulatory mechanisms regarding the manufacturing, distribution or sales of opioids. For example, in April 2018, New York enacted the Stewardship Act. See the principal risk "Our business and financial condition may be adversely affected by legislation" for more information. Many state legislatures are considering various bills intended to reduce opioid abuse such as by, for example, establishing prescription drug monitoring programs and mandating prescriber education.

Finally, various government entities, including Congress, state legislatures or other policy-making bodies may hold hearings, conduct investigations and/or issue reports calling attention to the opioid crisis, and may mention or criticize the role of manufacturers, including us, in the opioid crisis. Similarly, press organizations have and likely will continue to report on these issues, and such reporting may result in adverse publicity for manufacturers, including us.

Our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental drug pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions.

We are subject to federal and state laws prohibiting the presentation (or the causing to be presented) of claims for payment (by Medicare, Medicaid or other third-party payers) that are determined to be false or fraudulent, including presenting a claim for an item or service that was not provided. These false claims statutes include the federal civil False Claims Act, which permits private persons to bring suit in the name of the government alleging false or fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as *qui tam* actions, have increased significantly in the healthcare industry in recent years. These actions against pharmaceutical companies, which do not require proof of a specific intent to defraud the government, may result in payment of fines to and/or administrative exclusion from the Medicare, Medicaid and/or other government healthcare programs.

We are subject to laws that require us to enter into a Medicaid Drug Rebate Agreement and a 340B Pharmaceutical Pricing Agreement as a condition for having our products eligible for payment under Medicare Part B and Medicaid. We have entered into such agreements. In addition, we are required to report certain pricing information to the CMS, the Health Resources and Services Administration (HRSA) and the Department of Veterans Affairs (VA) on a periodic basis both to facilitate rebate payments to the State Medicaid Programs and to set Medicare Part B reimbursement levels and the prices that can be charged to certain purchasers, including 340B-covered entities and certain government entities.

With regard to the Medicaid Drug Rebate Program, on February 1, 2016, CMS issued a Final Rule implementing the Medicaid Drug Rebate provisions incorporated into the PPACA, effective April 1, 2016 in most instances. Implementation of the Final Rule required operational adjustments by us in order to maintain compliance with applicable law. Changes included in the Final Rule revised how manufacturers calculate Average Manufacturer Price and Best Price and also affect the quarterly amounts that we owe to state Medicaid programs through the Medicaid Drug Rebate program. In addition, CMS finalized its proposal to change the reimbursement metrics upon which Medicaid agencies are required to reimburse for covered outpatient drugs. The new reimbursement structure could adversely affect providers' reimbursement for our products, and thus could adversely affect sales of our products. The Final Rule also expanded the scope of the Medicaid Drug Rebate program to apply to U.S. territories, effective April 1, 2020, which will require operational adjustments and may result in additional rebate liability. Finally, CMS withdrew its proposed definition of "line extension" set forth in the 2012 proposed rule regarding the Medicaid Drug Rebate program and opened a new 60-day comment period soliciting views on how to interpret the relevant PPACA provisions. Nevertheless, the rules related to the definition of a "line extension" product have not been finalized. Additional operational adjustments and financial implications may result upon CMS's finalization of "line extension" provisions.

We and other pharmaceutical companies have been named as defendants in a number of lawsuits filed by various government entities, alleging generally that we and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable by state Medicaid programs, which are partially funded by the federal government. There is a risk we will be subject to similar investigations or litigations in the future, that we will suffer adverse decisions or verdicts of substantial amounts or that we will enter into monetary settlements. Any unfavorable outcomes as a result of such future litigation could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Decreases in the degree to which individuals are covered by healthcare insurance could result in decreased use of our products.

Employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees. Job losses or other economic hardships may also result in reduced levels of coverage for some individuals, potentially resulting in lower levels of healthcare coverage for themselves or their families. Further, in addition to the fact that the TCJA eliminated the PPACA's requirement that individuals maintain insurance or face a penalty, additional steps by the Trump Administration or other parties to limit or end cost-sharing subsidies to lower-income Americans may increase instability in the insurance marketplace and the number of uninsured Americans. These economic conditions may affect patients' ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations and lost healthcare insurance coverage or for other reasons. We believe such conditions could lead to changes in patient behavior and spending patterns that negatively affect usage of certain of our products, including some patients delaying treatment, rationing prescription medications, leaving prescriptions unfilled, reducing the frequency of visits to healthcare facilities, utilizing alternative therapies or foregoing healthcare insurance coverage. Such changes may result in reduced demand for our products, which could materially and adversely affect the sales of our products, our business, results of operations and cash flows.

In December 2018, Judge Reed O'Connor of the U.S. District Court for the Northern District of Texas held in *Texas v. Azar* that, because the provisions of the PPACA requiring certain individuals to either obtain health insurance or pay a shared responsibility payment are no longer permissible under the U.S. Congress' taxing power, the entire PPACA is no longer constitutional. While we expect that the decision will be appealed to the U.S. Court of Appeals for the Fifth Circuit, changes in law resulting from this ongoing lawsuit or other court challenges to the PPACA could materially and adversely affect the sales of our products, our business, results of operations and cash flows.

Our customer concentration may adversely affect our financial condition and results of operations.

We primarily sell our products to a limited number of wholesale drug distributors and retail drug store chains. In turn, these wholesale drug distributors and retail drug store chains supply products to pharmacies, hospitals, governmental agencies and physicians. In addition, this distribution network is continuing to undergo significant consolidation marked by mergers and acquisitions among wholesale drug distributors and retail drug store chains. For example, McKesson Corporation and Wal-Mart Stores, Inc. are party to an agreement to jointly source generic pharmaceuticals and Express Scripts, through a wholly owned subsidiary, Innovative Product Alignment, LLC, announced it will participate in the Walgreens Boots Alliance Development GmbH group purchasing organization. We expect that consolidation of wholesale drug distributors and retail drug store chains will increase pricing and other competitive pressures on pharmaceutical companies, including us. Additionally, the emergence of large buying groups representing independent retail pharmacies and other drug distributors, and the prevalence and influence of managed care organizations and similar institutions increases the negotiating power of these groups, potentially enabling them to attempt to extract price discounts, rebates and other restrictive pricing terms on our products.

Total turnover from direct customers who accounted for 10% or more of our total consolidated turnover during the years ended December 31, 2018 and 2017 are as follows:

	2018	2017
AmerisourceBergen Corporation	32%	25%
McKesson Corporation	27%	25%
Cardinal Health, Inc.	26%	25%

Turnover from these customers are included within each of our segments. Accordingly, our turnover, financial condition or results of operations may also be unduly affected by fluctuations in the buying or distribution patterns of these customers. These fluctuations may result from seasonality, pricing, wholesaler stock objectives or other factors. In addition, if we were to lose the business of any of these customers, or if any were to experience difficulty in paying us on a timely basis, our total turnover, profitability and cash flows could be materially adversely affected.

We are currently dependent on outside manufacturers for the manufacture of a significant amount of our products; therefore, we have and will continue to have limited control of the manufacturing process and related costs. Certain of our manufacturers currently constitute the sole source of one or more of our products.

Third party manufacturers currently manufacture a significant amount of our products pursuant to contractual arrangements. Certain of our manufacturers currently constitute the sole source of our products. For example, Teikoku Seiyaku Co., Ltd. is our sole source of LIDODERM® and GlaxoSmithKline plc is our sole source of VOLTAREN® Gel. Because of contractual restraints and the lead-time necessary to obtain FDA approval and/or Drug Enforcement Administration registration of a new manufacturer, there are no readily accessible alternatives to these manufacturers and replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of products to customers. Our business and financial viability are dependent on these third party manufacturers for continued manufacture of our products, the continued regulatory compliance of these manufacturers and the strength, validity and terms of our various contracts with these manufacturers. Any interruption or failure by these manufacturers to meet their obligations pursuant to various agreements with us on schedule or in accordance with our expectations, or any termination by these manufacturers of our supply arrangements, which, in each case, could be the result of one or many factors outside of our control, could delay or prevent our ability to achieve sales expectations, cause interruptions in our supply of products to customers, cause us to incur failure-to-supply penalties, disrupt our operations or cause reputational harm to our company, any or all of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We are dependent on third parties to supply all raw materials used in our products and to provide services for certain core aspects of our business. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We rely on third parties to supply all raw materials used in our products. In addition, we rely on third party suppliers, distributors and collaboration partners to provide services for certain core aspects of our business, including manufacturing, warehousing, distribution, customer service support, medical affairs services, clinical studies, sales and other technical and financial services. All third party suppliers and contractors are subject to FDA, and very often DEA, requirements. Our business and financial viability are dependent on the continued supply of goods and services by these third party suppliers, the regulatory compliance of these third parties and on the strength, validity and terms of our various contracts with these third party manufacturers, distributors and collaboration partners. Any interruption or failure by our suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us on schedule or in accordance with our expectations, which could be the result of one or many factors outside of our control, could delay or prevent the development, approval, manufacture or commercialization of our products, result in non-compliance with applicable laws and regulations, cause us to incur failure-to-supply penalties, disrupt our operations or cause reputational harm to our company, any or all of which could have a material adverse effect on our business, financial condition, results of operations and cash flows. We may also be unsuccessful in resolving any underlying issues with such suppliers, distributors and partners or replacing them within a reasonable time and on commercially reasonable terms.

All APIs imported into the European Union (EU) must be certified as complying with the good manufacturing practice standards established by the EU, as stipulated by the International Conference for Harmonization. These regulations place the certification requirement on the regulatory bodies of the exporting countries. Accordingly, the national regulatory authorities of each exporting country must: (i) ensure that all manufacturing plants within their borders that export API into the EU comply with EU manufacturing standards and (ii) for each API exported, present a written document confirming that the exporting plant conforms to EU manufacturing standards. The imposition of this responsibility on the governments of the nations exporting API may cause a shortage of API necessary to manufacture our products, as certain governments may not be willing or able to comply with the regulation in a timely fashion, or at all. A shortage in API may cause us to cease manufacturing of certain products or to incur costs and delays to qualify other suppliers to substitute for those API manufacturers unable to export. This could adversely affect the Group and could have a material adverse effect on our business, results of operations, financial condition and cash flow.

We are dependent upon third parties to provide us with various estimates as a basis for our financial reporting. While we undertake certain procedures to review the reasonableness of this information, we cannot obtain absolute assurance over the accounting methods and controls over the information provided to us by third parties. As a result, we are at risk of them providing us with erroneous data which could have a material adverse impact on our business and or reporting.

If our manufacturing facilities are unable to manufacture our products or the manufacturing process is interrupted due to failure to comply with regulations or for other reasons, it could have a material adverse impact on our business.

If any of our or our third party manufacturing facilities fail to comply with regulatory requirements or encounter other manufacturing difficulties, it could adversely affect our ability to supply products. All facilities and manufacturing processes used for the manufacture of pharmaceutical products are subject to inspection by regulatory agencies at any time and must be operated in conformity with cGMP and, in the case of controlled substances, DEA regulations. Compliance with the FDA's cGMP and DEA requirements applies to both drug products seeking regulatory approval and to approved drug products. In complying with cGMP requirements, pharmaceutical manufacturing facilities must continually expend significant time, money and effort in production, recordkeeping, quality assurance and quality control so that their products meet applicable specifications and other requirements for product safety, efficacy and quality. Failure to comply with applicable legal requirements subjects our or our third party manufacturing facilities to possible legal or regulatory action, including shutdown, which may adversely affect our ability to supply the product. Additionally, our or our third party manufacturing facilities may face other significant disruptions due to labor strikes, failure to reach acceptable agreement with labor unions, infringement of intellectual property rights, vandalism, natural disaster, storm or other environmental damage, civil or political unrest, export or import restrictions or other events. Were we not able to manufacture products at our or our third party manufacturing facilities because of regulatory, business or any other reasons, the manufacture and marketing of these products would be interrupted. This could have a material adverse impact on our business, results of operation, financial condition, cash flows and competitive position.

For example, the manufacturing facilities that are qualified to manufacture CCH, which we sell under the trademark XIAFLEX® and may use from time to time in the research and development of CCH for other investigational indications, such as for cellulite, are subject to such regulatory requirements and oversight. If such facilities fail to comply with cGMP requirements, we may not be permitted to sell our products or may be limited in the jurisdictions in which we are permitted to sell them. Further, if an inspection by regulatory authorities indicates that there are deficiencies, including non-compliance with regulatory requirements, we could be required to take remedial actions, stop production or close our facilities, which would disrupt the manufacturing processes, limit the supply of CCH and delay clinical trials and subsequent licensure and/or limit the sale of commercial supplies. In addition, future noncompliance with any applicable regulatory requirements may result in refusal by regulatory authorities to allow use of CCH in clinical trials, refusal of the government to allow distribution of CCH within the U.S. or other jurisdictions, criminal prosecution, fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products, refusal to allow the entering into of federal and state supply contracts and follow-on civil litigation.

We purchase certain API and other materials used in our manufacturing operations from foreign and domestic suppliers. The price of API and other materials is subject to volatility. There is no guarantee that we will always have timely, sufficient or affordable access to critical raw materials or supplies from third parties. An increase in the price, or an interruption in the supply, of any API or raw material, could cause our business, financial condition, results of operations and cash flows to be materially adversely affected.

The DEA limits the availability of the active ingredients used in many of our products as well as the production of these products, and, as a result, our procurement and production quotas may not be sufficient to meet commercial demand or complete clinical trials.

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our products are listed by the DEA as Schedule II or III substances under the CSA. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, generally, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the DEA limits the availability of the active ingredients used in many of our products and sets a quota on the production of these products. We, or our contract manufacturing organizations, must annually apply to the DEA for procurement and production quotas in order to obtain these substances and produce our products. On October 24, 2018, H.R. 6 was signed into law. Among other things, H.R. 6 amends the Controlled Substances Act with respect to quotas by requiring the DEA to estimate the amount and impact of diversion (including overdose deaths and abuse and overall public health impact) of fentanyl, oxycodone, hydrocodone, oxymorphone or hydromorphone (which we refer to collectively herein as "covered controlled substances") and to make appropriate quota reductions. As a result, our procurement and production quotas may not be sufficient to meet commercial demand or to complete clinical trials. Moreover, the DEA may adjust these quotas from time to time during the year. Any delay or refusal by the DEA in establishing our quotas, or modification of our quotas, for controlled substances could delay or result in the stoppage of our clinical trials or product launches, or could cause trade stock disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position, results of operations and cash flows.

If we are unable to retain our key personnel and continue to attract additional professional staff, we may be unable to maintain or expand our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical and commercial personnel. The loss of key scientific, technical and commercial personnel or the failure to recruit additional key scientific, technical and commercial personnel could have a material adverse effect on our business. While we have consulting agreements with certain key individuals and institutions and have employment agreements with our key executives, we may be unsuccessful in retaining personnel or their services under existing agreements. There is intense competition for qualified personnel in the areas of our activities and we may be unable to continue to attract and retain the qualified personnel necessary for the development of our business.

The trading prices of our securities may be volatile, and investments in our securities could decline in value.

The market prices for securities of Endo, and of pharmaceutical companies in general, have been highly volatile and may continue to be highly volatile in the future. For example, in 2018, our ordinary shares traded between $5.27 and $18.50 per share on the NASDAQ. The following factors, in addition to other principal risks described in this section, may cause the market value of our securities to fluctuate:

- FDA approval or disapproval of any of the drug applications we have submitted;
- the success or failure of our clinical trials;

- new data or new analyses of older data that raises potential safety or effectiveness issues concerning our approved products;
- product recalls or withdrawals;
- competitors announcing technological innovations or new commercial products;
- introduction of generic or compounded substitutes for our products, including the filing of ANDAs with respect to generic versions of our branded products;
- developments concerning our or others' proprietary rights, including patents;
- competitors' publicity regarding actual or potential products under development or other activities affecting our competitors or the industry in general;
- regulatory developments in the U.S. and foreign countries, or announcements relating to these matters;
- period-to-period fluctuations in our financial results;
- new legislation, regulation, administrative guidance or executive orders, or changes in interpretation of existing legislation, regulation, administrative guidance or executive orders, including by virtue of new judicial decisions, that could affect the development, sale or pricing of pharmaceutical products; the number of individuals with access to affordable healthcare; the taxes we pay and/or other factors;
- a determination by a regulatory agency that we are engaging or have engaged in inappropriate sales or marketing activities, including promoting off-label uses of our products;
- social and political pressure to lower the cost of drugs;
- social and political scrutiny over increases in prices of shares of pharmaceutical companies that are perceived to be caused by a strategy of growth through acquisitions;
- litigation; and
- changes in the political and regulatory environment and international relations as a result of events such as the exit of the United Kingdom from the European Union (Brexit) and full or partial shutdowns of the U.S. federal government that may occur from time to time, the current U.S. administration and other external factors, including market speculation or disasters and other crises.

We have no plans to pay regular dividends on our ordinary shares or to conduct ordinary share repurchases.

While our Board of Directors will regularly review our dividend policy, we currently do not intend to pay any cash dividends in the foreseeable future on our ordinary shares. Additionally, while the Board of Directors has approved the 2015 Share Buyback Program, of which there is approximately $2.3 billion available as of December 31, 2018, we currently do not intend to conduct ordinary share repurchases in the foreseeable future. Any declaration and payment of future dividends to holders of ordinary shares as well as any repurchase of our ordinary shares under the 2015 Share Buyback Program will be at the sole discretion of our Board of Directors and will depend on many factors, including our financial condition, earnings, capital requirements, level of indebtedness, statutory and contractual restrictions applying to the payment of both cash and property dividends or share repurchases and other considerations that our Board of Directors deems relevant. For example, the Companies Act requires Irish companies to have distributable reserves equal to or greater than the amount of any proposed dividend or share repurchase. Unless we are able to generate sufficient distributable reserves from our business activities, the creation of such distributable reserves would involve a reduction of our share premium account, which would require the approval of (i) 75% of our shareholders present and voting at a shareholder meeting and (ii) the Irish High Court. In addition, our existing debt instruments restrict or prevent us from paying dividends on our ordinary shares and conducting ordinary share repurchases. Agreements governing any future indebtedness, in addition to those governing our current indebtedness, may not permit us to pay dividends on our ordinary shares or conduct ordinary share repurchases.

Our operations could be disrupted if our information systems fail, if we are unsuccessful in implementing necessary upgrades or if we are subject to cyber-attacks.

Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. As such, we continuously invest financial and other resources to maintain, enhance, further develop, replace or add to our information technology infrastructure. For example, we are currently in the process of making changes to our enterprise resource planning (ERP) systems and related software to improve the efficiency and effectiveness of the managing of our business and financial operations. Such changes carry risks such as cost overruns, project delays and business interruptions, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. Additionally, these measures are not guaranteed to protect against all cybersecurity incidents.

In the ordinary course of our business operations, we collect and maintain information, which includes confidential and proprietary information as well as personal information regarding our customers and employees, in digital form. Data maintained in digital form is subject to risk of cyber-attacks, which are increasing in frequency and sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups, "hackers" and others. Cyber-attacks could include the deployment of harmful malware, viruses, worms, denial-of-service attacks, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Despite our efforts to monitor and safeguard our systems to prevent data compromise, the possibility of a future data compromise cannot be eliminated entirely, and risks associated with intrusion, tampering and theft remain. In addition, we do not have insurance coverage with respect to system failures or cyber-attacks. If our systems were to fail or we are unable to successfully expand the capacity of these systems, or we are unable to integrate new technologies into our existing systems, our operations and financial results could suffer.

We also have outsourced certain elements and functions of our operations, including elements of our information technology infrastructure, to third parties, some of which are outside the U.S. As a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our and our vendors' systems make such systems potentially vulnerable to service interruptions. The size and complexity of our and our vendors' systems and the large amounts of confidential information that is present on them also makes them potentially vulnerable to security breaches from inadvertent or intentional actions by our employees, our partners, our vendors or other third parties, or from attacks by malicious third parties.

The Group and its vendors' sophisticated information technology operations are spread across multiple, sometimes inconsistent platforms, which pose difficulties in maintaining data integrity across systems. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional or improper dissemination or destruction of confidential information stored in the Group's systems.

A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business and reputational harm to the Group and could have a material adverse effect on our turnover, financial condition or results of operations.

In addition, legislators and/or regulators in countries in which we operate are increasingly adopting or revising privacy, information security and data protection laws (Privacy Laws). In particular, the European Union's General Data Protection Regulation (GDPR), which became enforceable on May 25, 2018, has extra-territorial scope and substantial fines for breaches (up to 4% of global annual turnover or €20 million, whichever is greater). Enforcement of Privacy Laws also has increased over the past few years. Accordingly, new and revised Privacy Laws, together with stepped-up enforcement of existing Privacy Laws, could significantly affect our current and planned privacy, data protection and information security-related practices, our collection, use, sharing, retention and safeguarding of consumer and/or employee information and some of our current or planned business activities. Any failure to comply with Privacy Laws, could lead to government enforcement actions and significant sanctions or penalties against us, adversely impact our results of operations and subject us to negative publicity.

Foreign regulatory requirements vary, including with respect to the regulatory approval process, and failure to obtain regulatory approval or maintain compliance with requirements in foreign jurisdictions would prevent or impact the marketing of our products in those jurisdictions.

We have worldwide intellectual property rights to market many of our products and product candidates and intend to seek approval to market certain of our existing or potential future products outside of the U.S. Approval of a product by the regulatory authorities of foreign countries is generally required prior to manufacturing or marketing that product in those countries. The approval procedure varies among countries and can involve additional testing and the time required to obtain such approval may differ from that required to obtain FDA approval. Non-U.S. regulatory approval processes generally include risks similar to those associated with obtaining FDA approval, as further described herein. Approval by the FDA does not secure approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country secure approval by regulatory authorities in other foreign countries or by the FDA.

Outside of the U.S., regulatory agencies generally evaluate and monitor the safety, efficacy and quality of pharmaceutical products and devices and impose regulatory requirements applicable to manufacturing processes, stability testing, recordkeeping and quality standards, among others. These requirements vary by jurisdiction. In certain countries, including emerging and developing markets, the applicable healthcare and drug regulatory regimes are continuing to evolve and new requirements may be implemented. Ensuring and maintaining compliance with these evolving requirements is and will continue to be difficult, time-consuming and costly. In seeking regulatory approvals in non-U.S. jurisdictions, we must also continue to comply with U.S. laws and regulations, including those imposed by the U.S. Foreign Corrupt Practices Act (FCPA). See the principal risk "The risks related to our global operations may adversely impact our turnover, results of operations and financial condition." If we fail to comply with these various regulatory requirements or fail to obtain and maintain required approvals, our target market will be reduced and our ability to generate turnover from abroad will be adversely affected.

We could be adversely affected by the risks related to our Astora business, which previously manufactured medical devices.

We are subject to various risks associated with having operated a medical device manufacturing business, which risks could have adverse effects, including potential and actual product liability claims for any defective or allegedly defective goods that were distributed and increased government scrutiny and/or potential claims regarding the marketing of medical devices.

We are subject to health information privacy and data protection laws that include penalties for noncompliance.

We are subject to a number of privacy and data protection laws and regulations globally. The legislative and regulatory landscape for privacy and data security continues to evolve. There has been increased attention to privacy and data security issues in both developed and emerging markets with the potential to directly affect our business. This includes federal and state laws and regulations in the U.S. as well as in Europe and other markets. There has also been increased enforcement activity in the U.S. particularly related to data security breaches. A violation of these laws or regulations by us or our third party vendors could subject us to penalties, fines, liability and/or possible exclusion from Medicare or Medicaid. Such sanctions could materially and adversely affect our business, results of operations, financial condition and cash flows.

Our international operations could expose us to various risks, including risks related to fluctuations in foreign currency exchange rates.

In 2018, approximately 5% of our total turnover was from customers outside the U.S. Some of these sales were to governmental entities and other organizations with extended payment terms. A number of factors, including differing economic conditions, changes in political climate, differing tax regimes, changes in product pricing, changes in diplomatic and trade relationships and political or economic instability in the countries where we do business, could affect payment and credit terms and our ability to collect foreign receivables. A substantial slowdown of the global economy, or major national economies, could negatively affect growth in the markets in which we operate. Such a slowdown could result in national governments making significant cuts to their public spending, including national healthcare budgets, or reducing the level of reimbursement they are willing and able to provide to us for our products and, as a result, adversely affect our turnover, financial condition or results of operations. We have little influence over these factors and changes could have a material adverse impact on our business. In particular, the risk of a debt default by one or more European countries and related European or national financial restructuring efforts may cause volatility in the value of the euro. In addition, foreign sales are influenced by fluctuations in currency exchange rates, primarily the Canadian dollar, euro and British pound. Furthermore, we conduct certain of our manufacturing, research and development and other operations in India, which subjects us to various risks, including those related to fluctuations in the exchange rate for the Indian rupee.

We face risks relating to the expected exit of the United Kingdom from the European Union.

On June 23, 2016, the United Kingdom held a remain-or-leave referendum on the United Kingdom's membership within the European Union, the result of which favored the Brexit. On March 29, 2017, the Prime Minister of the United Kingdom delivered a formal notice of withdrawal to the European Union. On May 22, 2017, the Council of the European Union (the Council), adopted a decision authorizing the opening of Brexit negotiations with the United Kingdom and formally nominated the European Commission as the European Union negotiator. The Council also adopted negotiating directives for the talks. The negotiation has begun and is expected to involve a process of lengthy negotiations which will likely determine the future terms of the United Kingdom's relationship with the European Union, as well as whether the United Kingdom will be able to continue to benefit from the European Union's free trade and similar agreements. The negotiation of the withdrawal agreement has been, to date, a lengthy and contentious process and we do not, as at the date of this Annual Report, have certainty as to the terms of the United Kingdom's future relationship with the European Union. The timing of the Brexit is uncertain and potential impact of Brexit on our market share, sales, profitability and results of operations is unclear. If the United Kingdom were to significantly alter its regulations affecting the pharmaceutical industry, we could face significant new costs. It may also be time-consuming and expensive for us to alter our internal operations in order to comply with new regulations. In addition, since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate turnover and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business. Similarly, it is unclear at this time what Brexit's impact will have on our intellectual property rights and the process for obtaining and defending such rights. It is possible that certain intellectual property rights, such as trademarks, granted by the European Union will cease being enforceable in the United Kingdom absent special arrangements to the contrary. Additionally, depending on the terms of Brexit, economic conditions in the United Kingdom, the European Union and global markets may be adversely affected by reduced growth and volatility. The uncertainty both during and after the period of negotiation is also expected to have a negative economic impact and increase volatility in the markets, particularly in the Eurozone. Such volatility and negative economic impact could, in turn, adversely affect the Group's business, results of operations, financial condition and cash flows.

The risks related to our global operations may adversely impact our turnover, results of operations and financial condition.

Our operations extend to numerous countries outside the U.S. and are subject to the risks of conducting business globally. Conducting business internationally, including the sourcing, manufacturing, development, sale and distribution of our products and services across international borders, subjects us to extensive U.S. and foreign governmental trade regulations, such as various anti-bribery laws, including the FCPA, export control laws, customs and import laws, and anti-boycott laws. The FCPA and similar anti-corruption laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to government officials for the purpose of obtaining or retaining business. We cannot provide assurance that our internal controls and procedures will always protect us from criminal acts committed by our employees or third parties with whom we work. If we are found liable for violations of the FCPA or other applicable laws and regulations, either due to our own acts or out of inadvertence, or due to the acts or inadvertence of others, we could suffer significant criminal, civil and administrative penalties, including, but not limited to, imprisonment of individuals, fines, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting, as well as reputational harm. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

In addition, some countries in which our subsidiaries develop, manufacture or sell products are subject to political, economic and/or social instability. Our non-U.S. R&D, manufacturing and sales operations expose us and our employees, representatives, agents and distributors to risks inherent in operating in non-U.S. jurisdictions. For example, in early 2018, we shifted certain of our U.S. R&D functions to India. We also manufacture certain of our products in India and expect that our Indian manufacturing operations could expand in the future. A disruption in our Indian operations could have a material adverse effect on our results of operations and financial condition. These risks include:

- the imposition of additional U.S. and non-U.S. governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. and/or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;
- economic and political instability or disruptions, including local and regional instability, or disruptions due to natural disasters, such as severe weather and geological events, disruptions due to civil unrest and hostilities, rioting, military activity, terror attacks or armed hostilities;

- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions including foreign exchange controls;
- supply disruptions and increases in energy and transportation costs;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- changes in global tax laws and/or the imposition by tax authorities of significant fines, penalties and additional taxes;
- pricing pressure that we may experience internationally;
- fluctuations in foreign currency exchange rates;
- competition from local, regional and international competitors;
- difficulties and costs of staffing and managing foreign operations, including cultural differences and additional employment regulations, union workforce negotiations and potential disputes in the jurisdictions in which we operate;
- laws and business practices favoring local companies;
- difficulties in enforcing or defending intellectual property rights; and
- exposure to different legal and political standards due to our conducting business in foreign countries.

We also face the risk that some of our competitors have more experience with operations in such countries or with international operations generally and may be able to manage unexpected crises more easily. Furthermore, whether due to language, cultural or other differences, public and other statements that we make may be misinterpreted, misconstrued or taken out of context in different jurisdictions. Moreover, the internal political stability of, or the relationship between, any country or countries where we conduct business operations may deteriorate, including relationships between the U.S. and other countries. Changes in a country's political stability or the state of relations between any such countries are difficult to predict and could adversely affect our operations. Any such changes could lead to a decline in our profitability and/or adversely impact our ability to do business. Any meaningful deterioration of the political or social stability in and/or diplomatic relations between any countries in which we or our partners and suppliers do business could have a material adverse effect on our operations.

We cannot provide assurance that one or more of these factors will not harm our business. Any material decrease in our non-U.S. R&D, manufacturing or sales could adversely impact our results of operations and financial condition.

We have a substantial amount of indebtedness which could adversely affect our financial position and prevent us from fulfilling our obligations under such indebtedness, which may require us to refinance all or part of our then outstanding indebtedness. Any refinancing of this substantial indebtedness could be at significantly higher interest rates. Additionally, we have a significant amount of floating rate indebtedness and an increase in interest rates would increase the cost of servicing our indebtedness. Despite our current level of indebtedness, we may still be able to incur substantially more indebtedness. This could increase the risks associated with our substantial indebtedness.

We currently have a substantial amount of indebtedness. As of December 31, 2018, we have total debt of approximately $8.35 billion in aggregate principal amount. Our substantial indebtedness may:

- make it difficult for us to satisfy our financial obligations, including making scheduled principal and interest payments on our indebtedness;
- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;
- expose us to the risk of rising interest rates with respect to the borrowings under our variable rate indebtedness;
- require us to use a substantial portion of our cash on hand and/or from future operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

If we are unable to pay amounts due under our outstanding indebtedness or to fund other liquidity needs, such as future capital expenditures or contingent liabilities as a result of adverse business developments, including expenses related to our ongoing and future legal proceedings and governmental investigations as well as increased pricing pressures or otherwise, we may be required to refinance all or part of our then existing indebtedness, sell assets, reduce or delay capital expenditures or seek to raise additional capital, any of which could have a material adverse effect on our operations. There can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all. Any refinancing of this substantial indebtedness could be at significantly higher interest rates, which will depend on the conditions of the markets and our financial condition at such time. In addition, we and our subsidiaries may be able to incur substantial additional indebtedness in the future. If new indebtedness is added to our current debt levels, the related risks that we and our subsidiaries now face could intensify.

While interest rates have been at record low levels in recent years, this low interest rate environment likely will not continue indefinitely. In March, June, September and December 2018, the U.S. Federal Reserve raised its benchmark interest rate by a quarter of a percentage point, respectively. At December 31, 2018, approximately $3.4 billion of principal outstanding under the Term Loan Facility (as defined below) bears interest at floating rates. We also have $997.3 million of remaining credit available through the Revolving Credit Facility (as defined below) at December 31, 2018. If we borrow amounts under our Revolving Credit Facility, such borrowings could also bear interest at floating rates. As a result, to the extent we have not hedged against rising interest rates, an increase in the applicable benchmark interest rates would increase our cost of servicing our indebtedness and could materially and adversely affect our business, results of operations, financial condition and cash flows.

Changes in the method of determining the London Interbank Offered Rate (LIBOR), or the replacement of LIBOR with an alternative reference rate, may materially adversely affect our interest expense related to our outstanding debt.

A significant portion of our outstanding indebtedness, including $3.4 billion outstanding under the Term Loan Facility at December 31, 2018, bears interest rates in relation to LIBOR. Any future amounts borrowed under the Term Loan Facility or drawn under the Revolving Credit Facility would also bear interest rates in relation to LIBOR, depending on our repayment election. On July 27, 2017, the Financial Conduct Authority (FCA) in the United Kingdom announced that it would phase out LIBOR as a benchmark by the end of 2021. It is unclear whether, at that time, LIBOR will cease to exist or whether new methods of calculating LIBOR will be established such that it continues to exist after 2021. In the U.S., efforts to identify a set of alternative U.S. dollar reference interest rates include proposals by the Alternative Reference Rates Committee of the Federal Reserve Board and the Federal Reserve Bank of New York. If LIBOR ceases to exist, we may need to renegotiate the Credit Agreement (as defined below) and we may not be able to do so on terms that are favorable to us. The overall financial market may be disrupted and there could be significant increases in benchmark rates or borrowing costs to borrowers as a result of the phase-out or replacement of LIBOR. Disruption in the financial market, significant increases in benchmark rates or borrowing costs or our inability to refinance the Credit Agreement with favorable terms could have a material adverse effect on our business, financing activities, financial condition and operations.

Covenants in our debt agreements restrict our business in many ways, a default of which may result in acceleration of certain of our indebtedness.

We are subject to various covenants in the instruments governing our debt that limit our ability and/or our restricted subsidiaries' ability to, among other things:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- issue redeemable stock and preferred stock;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase debt;
- make loans, investments and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

A breach of any of these covenants could result in a default under our indebtedness. If there were an event of default under any of the agreements relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately, terminate all commitments to extend further credit, foreclose against all the assets comprising the collateral securing or otherwise supporting the debt and pursue other legal remedies. The instruments governing our debt contain cross-default or cross-acceleration provisions that may cause all of the debt issued under such instruments to become immediately due and payable as a result of a default under an unrelated debt instrument. An event of default or an acceleration under one debt agreement could cause a cross-default or cross-acceleration of other debt agreements. Our assets and cash flows may be insufficient to fully repay borrowings under our outstanding debt instruments if the obligations thereunder were accelerated upon an event of default. We may need to conduct asset sales or elect to pursue other alternatives, including proceedings under applicable insolvency laws relating to some or all of our business. Any or all of the above could have a material adverse effect on our business, financing activities, financial condition and operations. For a description of our indebtedness, see Note 12. Debt of the accompanying Consolidated Financial Statements included in this report.

U.S. federal income tax reform could adversely affect us.

On December 22, 2017, U.S. federal tax legislation, commonly referred to as the TCJA, was signed into law, significantly altering the U.S. Internal Revenue Code effective, in substantial part, January 1, 2018. The TCJA, among other things, includes:

- changes to U.S. federal tax rates;

- expanded limitations on the deductibility of interest;
- immediate expensing of capital expenditures;
- the migration from a "worldwide" system of taxation to a "territorial" system;
- the creation of an anti-base erosion minimum tax system; and
- the modification or repeal of many business deductions and credits.

Additionally, the TCJA eliminates the ability to carry back any future net operating losses and only allows for carryforwards, the utilization of which is limited to 80% of taxable profit in a given carryforward year. This could affect the timing of our ability to utilize net operating losses in the future.

The aforementioned changes could, individually or in aggregate, increase our future effective tax rate and adversely impact our results of operations and cash flows from operations. Finally, prospective or retroactive regulatory and administrative guidance relating to the TCJA could adversely impact our businesses and our current and future projections of U.S. cash taxes.

Further future changes to tax laws could materially adversely affect us.

Under current law, we are expected to be treated as a non-U.S. corporation for U.S. federal income tax purposes. However, changes to the rules in Section 7874 of the Internal Revenue Code (the Code) or regulations promulgated thereunder or other guidance issued by the Treasury or the U.S. Internal Revenue Service (IRS) could adversely affect our status as a non-U.S. corporation for U.S. federal income tax purposes, and any such changes could have prospective or retroactive application to us, Endo Health Solutions Inc. (EHSI) and/or their respective shareholders and affiliates. Consequently, there can be no assurance that there will not exist in the future a change in law that might cause us to be treated as a U.S. corporation for U.S. federal income tax purposes, including with retroactive effect.

In addition, recent Irish legislation created a "controlled foreign corporation" tax regime and future proposals may limit deductibility of certain interest and/or other payments made by our Irish subsidiaries from which we currently benefit. If such changes in law were enacted, it could have a material adverse effect on our financial statements and cash flow from operations.

In addition, Ireland's Department of Finance, Luxembourg's Ministry of Finance, the Organization for Economic Co-operation and Development, the European Commission and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations and there are several current proposals that, if enacted, would substantially change the taxation of multinational corporations. One example is in the area of "base erosion and profit shifting," where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. As a result, the tax laws in the jurisdictions in which we operate could change on a prospective or retroactive basis, and any such changes, including those related to the allocation of profit among our subsidiaries, could increase our effective tax rate, which could have a materially adverse impact on our financial statements and cash flows from operations.

The IRS may not agree with the conclusion that we should be treated as a non-U.S. corporation for U.S. federal income 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 income tax purposes pursuant to Section 7874 of the Code. A corporation is generally considered a tax resident in the jurisdiction of its organization or incorporation for U.S. federal income tax purposes. Because we are an Irish incorporated entity, we would generally be classified as a non-U.S. corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 provides an exception pursuant to which a non-U.S. incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal income tax purposes.

Under Section 7874, we would be treated as a non-U.S. corporation for U.S. federal income tax purposes if the former shareholders of EHSI owned, immediately after the Paladin transaction (within the meaning of Section 7874), less than 80% (by both vote and value) of Endo shares by reason of holding shares in EHSI (the ownership test). The former EHSI shareholders owned less than 80% (by both vote and value) of the shares in Endo after the Paladin merger by reason of their ownership of shares in EHSI. As a result, under current law, we are expected to be treated as a non-U.S. corporation for U.S. federal income tax purposes. There is limited guidance regarding the application of Section 7874, including with respect to the provisions regarding the application of the ownership test. Our obligation to complete the Paladin transactions was conditional upon its receipt of a Section 7874 opinion from our counsel, Skadden, Arps, Slate, Meagher & Flom LLP (Skadden), dated as of the closing date of the Paladin transaction and subject to certain qualifications and limitations set forth therein, to the effect that Section 7874 and the regulations promulgated thereunder should not apply in such a manner so as to cause Endo to be treated as a U.S. corporation for U.S. federal income tax purposes from and after the closing date. However, an opinion of tax counsel is not binding on the IRS or a court. Therefore, there can be no assurance that the IRS will not take a position contrary to Skadden's Section 7874 opinion or that a court will not agree with the IRS in the event of litigation.

The effective rate of taxation upon our results of operations is dependent on multi-national tax considerations.

We earn a portion of our profit outside the U.S. That portion of our earnings is taxed at the more favorable rates applicable to the activities undertaken by our subsidiaries outside of the U.S. Our effective income tax rate in the future could be adversely affected by a number of factors, including changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws, the outcome of income tax audits and the repatriation of earnings from our subsidiaries for which we have not provided for taxes. Cash repatriations are subject to restrictions in certain jurisdictions and may be subject to withholding and other taxes. We are subject to the examination of our tax returns and tax arrangements by the IRS and other tax and governmental authorities, such as described in the principal risk "We may not be able to successfully maintain our low tax rates or other tax positions, which could adversely affect our businesses and financial condition, results of operations and growth prospects." We regularly assess all of these matters to determine the adequacy of our tax provisions, which are subject to significant discretion. Although we believe our tax provisions are adequate, the final determination of tax audits and any related disputes could be materially different from our historical income tax provisions and accruals. The results of audits and disputes could have a material adverse effect on our financial statements for the period or periods for which the applicable final determinations are made.

Future changes in tax laws and rates, including further administrative or regulatory guidance related to the TCJA, could also affect recorded deferred tax assets and liabilities. Additionally, EU Member States that we operate in and/or have subsidiaries in continue to promulgate tax legislation in response to initiatives by the Economic and Financial Affairs Council of the EU. We continue to evaluate the potential impact of such legislation, which could have a material impact on the Group.

We may not be able to successfully maintain our low tax rates or other tax positions, which could adversely affect our businesses and financial condition, results of operations and growth prospects.

We are incorporated in Ireland and also maintain subsidiaries in, amongst other jurisdictions, the U.S., Canada, India, Bermuda, the United Kingdom and Luxembourg. The IRS and other taxing authorities may continue to challenge our tax positions. The IRS presently is examining certain of our subsidiaries' U.S. income tax returns for fiscal years ending between December 31, 2011 and December 31, 2015 and, in connection with those examinations, is reviewing our tax positions related to, among other things, certain intercompany arrangements, including the level of profit earned by our United States subsidiaries pursuant to such arrangements, and a worthless stock deduction directly attributable to product liability losses. The IRS may examine our tax returns for other fiscal years and/or for other tax positions. Similarly, other tax authorities may examine our non-U.S. tax returns and propose adjustments to our taxes. Such examinations may lead to proposed or actual adjustments to our taxes that may be material, individually or in the aggregate.

Responding to or defending any challenge or proposed adjustment to our tax positions is expensive, consumes time and other resources and diverts management's attention. We cannot predict whether taxing authorities will conduct an audit challenging any of our other tax positions, the cost involved in responding to and defending any such audit and resulting litigation, or the outcome. If we are unsuccessful in any of these matters, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future or repay certain tax refunds, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial position, results of operations and growth prospects.

Our ability to use U.S. tax attributes to offset U.S. taxable profit may be limited.

Existing and future tax laws and regulations may limit our ability to use U.S. tax attributes including, but not limited to, net operating losses and excess interest expense, to offset U.S. taxable profit. For a period of time following the 2014 Paladin transaction, Section 7874 of the Code precludes our U.S. affiliates from utilizing U.S. tax attributes to offset taxable profit if we complete certain transactions with related non-U.S. subsidiaries. In addition, the U.S. Treasury Department has issued temporary and proposed regulations related to corporate inversions and earnings stripping. The limitations on the use of certain tax attributes and deductions in these regulations are in addition to existing rules that could impose more restrictive limitations in the event that cumulative changes in our stock ownership within a three-year period exceed certain thresholds. Such changes or the adoption of additional limitations could impact our overall utilization of deferred tax assets, potentially resulting in a material adverse impact to our financial statements and cash flows from operations.

Any attempts to take us over will be subject to Irish Takeover Rules and subject to review by the Irish Takeover Panel.

We are subject to Irish Takeover Rules, under which our board of directors (the Board of Directors) will not be permitted to take any action which might frustrate an offer for our ordinary shares once it has received an approach which may lead to an offer or has reason to believe an offer is imminent.

If pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and other efforts, our sales of generic products may suffer.

Many pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

- pursuing new patents for existing products which may be granted just before the expiration of earlier patents, which could extend patent protection for additional years;
- using the Citizen Petition process (for example, under 21 C.F.R. s. 10.30) to request amendments to FDA standards;
- attempting to use the legislative and regulatory process to have drugs reclassified or rescheduled or to set definitions of abuse-deterrent formulations to protect patents and profits; and
- engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs.

If pharmaceutical companies or other third parties are successful in limiting the use of generic products through these or other means, our sales of generic products and our growth prospects may decline. If we experience a material decline in generic product sales, our results of operations, financial condition and cash flows will suffer.

We have limited experience in manufacturing biologic products and may encounter difficulties in our manufacturing processes, which could materially adversely affect our results of operations or delay or disrupt manufacture of those of our products that are reliant upon our manufacturing operations.

The manufacture of biologic products requires significant expertise and capital investment. Although we manufacture CCH, the active ingredient in XIAFLEX®, in our Horsham, Pennsylvania facility, we have limited experience in manufacturing CCH or any other biologic products. Biologics such as CCH require processing steps that are highly complex and generally more difficult than those required for most chemical pharmaceuticals. In addition, TESTOPEL® is manufactured using a unique, proprietary process. If the manufacturing processes are disrupted at the facilities where our biologic products are manufactured, it may be difficult to find alternate manufacturing sites. We may encounter difficulties with the manufacture of the active ingredient of XIAFLEX® or TESTOPEL®, which could delay, disrupt or halt our manufacture of XIAFLEX® and TESTOPEL®, respectively, result in product recalls or product liability claims, require write-offs which may affect our financial results, or otherwise materially affect our results of operations.

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

Our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction of the U.S. As an Irish company, we are governed by the Irish Companies Act 2014 (the Companies Act). The Companies Act and other relevant aspects of Irish law differ in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, the provisions relating to interested director and officer transactions, acquisitions, takeovers, shareholder lawsuits and indemnification of directors. For example, 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 generally do not have a personal right of action against the directors or officers of a company and may pursue a right of action on behalf of the company only in limited circumstances. In addition, depending on the circumstances, the acquisition, ownership and/or disposition of our ordinary shares may subject individuals to different or additional tax consequences under Irish law including, but not limited to, Irish stamp duty, dividend withholding tax and capital acquisitions tax.

We are an Irish company and it may be difficult to enforce judgments against us or certain of our officers and directors.

We are incorporated in Ireland and a substantial portion of our assets are located in jurisdictions outside the U.S. In addition, some of our officers and directors reside outside the U.S., and some or all of their respective assets are or may be located in jurisdictions outside of the U.S. Therefore, it may be difficult for investors to effect service of process against us or such officers or directors or to enforce against us or them judgments of U.S. courts predicated upon civil liability provisions of the U.S. federal securities laws.

There is no treaty between Ireland and the U.S. providing for the reciprocal enforcement of foreign judgments. The following requirements must be met before the foreign judgment will be deemed to be enforceable in Ireland:

- the judgment must be for a definite sum;
- the judgment must be final and conclusive; and
- the judgment must be provided by a court of competent jurisdiction.

An Irish court will also exercise its right to refuse judgment if the foreign judgment was obtained by fraud, if the judgment violated Irish public policy, if the judgment is in breach of natural justice or if it is irreconcilable with an earlier judgment. Further, an Irish court may stay proceedings if concurrent proceedings are being brought elsewhere. Judgments of U.S. courts of liabilities predicated upon U.S. federal securities laws may not be enforced by Irish courts if deemed to be contrary to public policy in Ireland.

Our failure to comply with various laws protecting the confidentiality of certain patient health information could result in penalties and reputational damage.

Certain countries in which we operate have, or are developing, laws protecting the confidentiality of individually identifiable personal information, including patient health information. EU member states and other jurisdictions have adopted data protection laws and regulations applicable to such information, which impose significant compliance obligations.

For example, as noted above, the GDPR, which replaced the pre-existing EU Data Protection Directive and became enforceable as of May 25, 2018, imposes strict restrictions on our authority to collect, analyze and transfer personal data regarding persons in the EU, including health data from clinical trials and adverse event reporting. The GDPR also grants individuals whose personal data (which is very broadly defined) is collected or otherwise processed the right to access the data, request its deletion and control its use and disclosure. The GDPR also requires notification of a breach in the security of such data to be provided within 72 hours of discovering the breach. Although the GDPR itself is self-executing across all EU member states, data protection authorities from different EU member states may interpret and apply the regulation somewhat differently, which adds to the complexity of processing personal data in the EU. To date, there has been very little interpretation of the regulation by the EU member states' different data protection authorities and little time for enforcement, which makes predicting future enforcement very difficult. That uncertainty contributes to liability exposure risk.

As did the pre-existing Data Protection Directive, the GDPR prohibits the transfer of personal data to countries outside of the EU that are not considered by the European Commission to provide an adequate level of data protection, and transfers of personal data to such countries may be made only in certain circumstances, such as where the transfer is necessary for important reasons of public interest or the individual to whom the personal data relates has given his or her explicit consent to the transfer after being informed of the risks involved.

We have policies and practices that we believe make us compliant with applicable privacy regulations, including the GDPR. Nevertheless, there remains a risk of failure to comply with the rules arising from the GDPR or privacy laws in other countries in which we operate. Should a transgression be deemed to have occurred, it could lead to government enforcement actions and significant sanctions or penalties against us, adversely impact our results of operations and subject us to negative publicity. Such liabilities could materially affect our operations.

Likely Future Developments

We estimate that the following factors will impact our 2019 total turnover as compared to 2018:

- growth in the Specialty Products portfolio of our U.S. Branded - Specialty & Established Pharmaceuticals segment, primarily driven by increased turnover following continued investments in XIAFLEX®;
- growth in the U.S. Branded - Sterile Injectables segment, driven by continued performance of VASOSTRICT® and ADRENALIN® and the full-year impact of ertapenem for injection, the authorized generic of Invanz®, which launched during the third quarter of 2018; and
- declines in the U.S. Generic Pharmaceuticals segment, the Established Products portfolio of the U.S. Branded - Specialty & Established Pharmaceuticals segment and the International Pharmaceuticals segment, primarily driven by continued competitive pressures impacting these product portfolios.

These estimated trends reflect the current expectations of the Group's management team based on information currently known to them. These estimates are subject to risks and uncertainties that could cause our actual results to differ materially from those indicated by such estimated trends.

Accounting Records

The directors are responsible for ensuring that Endo International plc (Company) and its subsidiaries keep accounting records and appropriate accounting systems. To achieve this, the directors have appointed a Chief Financial Officer who makes regular reports to the Board of Directors and ensures compliance with the requirements of Section 281 to 285 of the Companies Act, 2014. The Chief Financial Officer makes regular reports to the Audit Committee of the Board of Directors. The Audit Committee, in turn, briefs the full Board of Directors on significant financial matters arising from reports of the Chief Financial Officer and the external auditor. The measures taken by the directors to secure compliance with the Group's obligation to keep accounting records are the use of appropriate systems and procedures and employment of competent persons. The accounting records are kept at 1400 Atwater Drive, Malvern, PA 19355.

Significant Events Since Year End

Over-the-counter (OTC) Products

We recently received notice from a competing pharmaceutical company that manufactures one of our products that it intends to seek approval to launch a competing OTC version of such product. We are currently assessing the potential likelihood, timing and impact of any such launch, which could result in, among other things, a reduction of our net sales of such product and/or certain asset impairment charges that could be material. In addition, the Company has identified certain triggering events for the three months ended March 31, 2019 related to certain intangible assets and goodwill that will require the Company to test these assets for impairment. This analysis, which we expect to complete in connection with our first quarter 2019 financial reporting close, is expected to result in certain impairment charges, the amounts of which could be material.

March 2019 Refinancing

In March 2019, the Group executed several transactions (the March 2019 Refinancing Transactions), which included:

- the entry into an amendment (the Revolving Credit Facility Amendment) to the Group's existing credit agreement, which was originally dated April 27, 2017 (the Credit Agreement);
- the issuance of $1,500.0 million of 7.50% Senior Secured Notes due 2027 (the 2027 Notes);
- the repurchase of $1,642.2 million aggregate principal amount of certain of the Group's senior unsecured notes for $1,500.0 million in cash, excluding accrued interest (the Notes Repurchases); and
- the solicitation of consents from the holders of the existing 7.25% Senior Notes due 2022 and 5.75% Senior Notes due 2022 (together, the Consent Notes) to certain amendments to the indentures governing such notes, which eliminated substantially all of the restrictive covenants, certain events of default and other provisions contained in each such indenture.

The Revolving Credit Facility Amendment amended the Credit Agreement to, among other things, (i) extend the maturity of the commitments under the Revolving Credit Facility from April 2022 to March 2024 (with the exception of $76.0 million of commitments that were not extended), (ii) provide greater covenant flexibility by increasing the maximum Secured Net Leverage Ratio described in the Financial Covenant (as defined in the Credit Agreement) from 3.50:1.00 to 4.50:1.00 and (iii) limit the scenarios under which such Financial Covenant will be tested.

The 2027 Notes were issued by Par Pharmaceutical, Inc. (PPI), a wholly-owned subsidiary of the Company, in a private offering to "qualified institutional buyers" (as defined in Rule 144A under the Securities Act) and outside the U.S. to non-U.S. persons in compliance with Regulation S under the Securities Act. The 2027 Notes are guaranteed on a senior secured basis by the Company and its subsidiaries that also guarantee the Credit Agreement (collectively, the Guarantors). The 2027 Notes are senior secured obligations of PPI and the Guarantors and are secured by the same collateral that secures the Credit Agreement and the Company's existing senior secured notes. Interest on the 2027 Notes is payable semiannually in arrears on April 1 and October 1 of each year, beginning on October 1, 2019.

The 2027 Notes will mature on April 1, 2027; however, the indenture governing these notes allows for redemption prior to maturity, in whole or in part, subject to certain restrictions and limitations described therein, in the following ways:

- Before April 1, 2022, the 2027 Notes may be redeemed, in whole or in part, by paying the sum of: (i) 100% of the principal amount being redeemed, (ii) an applicable make-whole premium as described in the indenture and (iii) accrued and unpaid interest, if any, to, but not including, the date of redemption.
- On or after April 1, 2022, the 2027 Notes may be redeemed, in whole or in part, at redemption prices set forth in the indenture, plus accrued and unpaid interest, if any, to, but not including, the date of redemption. The redemption prices for the 2027 Notes vary over time pursuant to a step-down schedule set forth in the indenture, beginning at 105.625% of the principal amount redeemed and decreasing to 100% by April 1, 2025.
- Before April 1, 2022, the 2027 Notes may be redeemed, in part (up to 35% of the principal amount outstanding) with the net cash proceeds from specified equity offerings at 107.500% of the principal amount redeemed, plus accrued and unpaid interest, if any, to, but not including, the date of redemption.

The 2027 Notes indenture contains covenants that, among other things, restrict the Group's ability and the ability of its Restricted Subsidiaries (as defined in the indenture) to incur certain additional indebtedness and issue preferred stock; make certain dividends, distributions, investments and other restricted payments; sell certain assets; enter into sale and leaseback transactions; agree to certain restrictions on the ability of restricted subsidiaries to make certain payments to the Group or any of its restricted subsidiaries; create certain liens; merge, consolidate or sell all or substantially all of the Group's assets; enter into certain transactions with affiliates or designate subsidiaries as unrestricted subsidiaries. These covenants are subject to a number of exceptions and qualifications, including the fall away or revision of certain of these covenants and release of collateral upon the 2027 Notes receiving investment grade credit ratings.

The Group used the net proceeds of the 2027 Notes and cash at bank and in-hand primarily to fund the Notes Repurchases and to pay certain premiums, fees and expenses related thereto. The Notes Repurchases were completed by Endo Finance LLC (Endo Finance), a wholly-owned subsidiary of the Group, pursuant to a tender offer to repurchase portions of the Company's outstanding 7.25% Senior Notes due 2022, 5.75% Senior Notes due 2022, 5.375% Senior Notes due 2023 and 6.00% Senior Notes due 2023. In connection with the Notes Repurchases, Endo Finance repurchased $1,642.2 million of senior unsecured note indebtedness, representing the aggregate principal amount repurchased, for $1,500.0 million in cash (including certain cash premiums related thereto). The $1,642.2 million aggregate repurchase amount consisted of (i) $389.9 million aggregate principal amount of the 7.25% Senior Notes due 2022, (ii) $517.5 million aggregate principal amount of the 5.75% Senior Notes due 2022, (iii) $539.6 million aggregate principal amount of the 5.375% Senior Notes due 2023 and (iv) $195.2 million aggregate principal amount of the 6.00% Senior Notes due 2023. The aggregate carrying amount of notes repurchased was $1,624.0 million. In conjunction with the Notes Repurchases, Endo Finance also solicited consents from holders of the Consent Notes to certain proposed amendments to the applicable indentures under which each series of Consent Notes were issued, which would eliminate substantially all restrictive covenants, certain events of default and certain other provisions contained in each such indenture. The proposed amendments were effected pursuant to a supplemental indenture to each such indenture executed by Endo Finance and the guarantors of the Consent Notes, which became operative upon the repurchase of at least the requisite consent amount of the applicable series of Consent Notes tendered.

The difference between the cash paid and the carrying amount of notes repurchased in the Notes Repurchases resulted in a $124.0 million gain recorded as Gain on extinguishment of debt in the Consolidated Profit and Loss Account. In connection with the March 2019 Refinancing Transactions, we also incurred costs and fees totaling $26.2 million, of which $4.2 million related to the Notes Repurchases, $19.1 million related to the 2027 Notes issuance and $2.9 million related to the Revolving Credit Facility Amendment. The costs incurred in connection with the Notes Repurchases were charged to expense in the first quarter of 2019 and recorded as an offset to the Gain on extinguishment of debt. The costs incurred in connection with the 2027 Notes issuance and the Revolving Credit Facility Amendment, together with previously deferred debt issuance costs associated with the Revolving Credit Facility, have been deferred and will be amortized as interest expense over the terms of the respective instruments.

Directors and Secretary

The names of the persons who were directors at any time during the year ended December 31, 2018 are set out below. Unless indicated otherwise, they served as directors for the entire year.

Directors	Date of Service as Director or Secretary
Roger H. Kimmel	(Appointed 28 February 2014)
Paul Campanelli	(Appointed 23 September 2016)
Shane M. Cooke	(Appointed 29 July 2014)
Nancy J. Hutson, Ph.D.	(Appointed 28 February 2014)
Michael Hyatt	(Appointed 28 February 2014)
Sharad S. Mansukani, Ph.D.	(Appointed 08 November 2017)
William P. Montague	(Appointed 28 February 2014)
Todd B. Sisitsky	(Appointed 05 May 2016)
Jill D. Smith (1)	(Appointed 28 February 2014)
Secretary	
Orla Dunlea (2)	(Appointed 17 September 2014)
Yoon Ah Oh	(Appointed 28 June 2018)
Assistant Secretary	
Deanna Voss	(Appointed 28 February 2014)

(1) Jill D. Smith did not stand reelection at the Company's June 7, 2018 Annual Meeting due to her appointment as president and chief executive officer of another company. There were no disagreements between Ms. Smith and the Group, its management or the other directors on any matters relating to the Group's operations, policies or practices.

(2) Orla Dunlea resigned as secretary of the Company on June 28, 2018 and was replaced by Yoon Ah Oh.

Directors' and Secretary's Interests

No director, the secretary or any member of their immediate families had any interest in shares or debentures of any subsidiary. Directors' remuneration is set forth in Note 26. Directors' Remuneration of the accompanying Consolidated Financial Statements included in this report. The beneficial interests, including the interests of spouses and minor children, of the directors and secretary in office at December 31, 2018 in the share capital of Endo International plc were as follows:

	Ordinary Shares at 31 December 2018 (1)			Ordinary Shares at 1 January 2018 (or date of appointment if later) (1)		
Directors	Shares	Options (2)	Other Share Units (3)	Shares	Options (2)	Other Share Units (3)
Roger H. Kimmel	250,203	8,094	15,074	253,490	8,094	21,589
Paul Campanelli	344,138	2,008,234	2,284,772	216,132	1,036,644	908,011
Shane M. Cooke	56,244	—	—	41,224	—	—
Nancy J. Hutson, Ph.D.	43,455	13,185	6,515	37,183	13,185	6,515
Michael Hyatt	289,390	18,478	—	273,118	25,242	—
Sharad S. Mansukani, Ph.D.	43,540	—	—	27,268	—	—
William P. Montague	41,780	18,478	23,108	28,566	18,478	23,108
Todd B. Sisitsky (4)	—	—	—	—	—	—
Secretary						
Yoon Ah Oh (5)	4,302	20,183	32,866	2,608	20,183	35,233

(1) All interests declared are in the ordinary shares of $0.0001 par value of Endo International plc.

(2) Amounts include vested and unvested options.

(3) Amounts include vested and unvested restricted share units and performance share units.

(4) Mr. Sisitsky has waived all rights to receive any annual cash retainer fees, meeting fees, share-based awards, or other compensation of any kind (other than certain rights to indemnification, directors and officers insurance and expense reimbursement) in connection with his service as a director of the Group.

(5) Yoon Ah Oh was appointed secretary of the Company on June 28, 2018.

Dividends

The Group did not pay any dividends to ordinary shareholders and minority interests during 2018.

Political Donations

The electoral (Amendment) (Political Funding) Act 2012 requires companies to disclose all political donations over 200 euro in aggregate made during the financial year. The Directors, on inquiry, have satisfied themselves that no such donations have been made by the Group during the financial year.

NON-FINANCIAL STATEMENT

Endo's Business Model

A description of Endo's business model can be found under "Principal Activities" within this Report.

Our Commitment to Environmental, Social and Governance-Related Business Practices

At Endo, we believe that a commitment to positive environmental, social and governance-related business practices strengthens our company, increases our connection with our stakeholders and helps us better serve our customers and the communities in which we operate. We believe these commitments help to create value for our shareholders, our employees and our customers across the world. As a global company, Endo faces a range of risks, including general economic, credit and capital market conditions risks, regulatory risk, social and employee matters. A description of Endo's risks, including those related to environmental, social and governance issues can be found under "Principal Risks" within this Report.

We govern our enterprise risks and opportunities through a robust risk management and mitigation program. Our Board of Directors' (Board's) role in risk oversight is consistent with our leadership structure, with management having day-to-

day responsibility for identifying, assessing and managing our risk exposure and the Board and its committees providing oversight in connection with those efforts, with particular focus on the most significant risks we face. The Board performs its risk oversight role in several ways. Board meetings regularly include strategic overviews by the CEO that describe the most significant issues, including risks, affecting Endo. In addition, the Board is regularly provided with business updates from our business unit leaders and functional leaders. The board reviews the risks associated with our financial forecast, business plan and operations. These risks are identified and managed in connection with Endo's enterprise risk management (ERM) process.

As part of our ERM approach to risk management and our strategies for long-term value creation, our Board and our management monitor long-term risks and opportunities that may be impacted by environmental, social and governmental issues, set policies relating to these issues, and monitor the results of those policies. We monitor certain key metrics including those presented in this report.

The following is a summary of Endo's key policies and actions in the areas of (i) Environmental Matters, (ii) Social and Employee Matters, (iii) Human Rights and (iv) Bribery and Corruption. These policies and actions aim to confirm Endo's risk management in these areas and achieve its goals.

Focus on Ethics

Endo's reputation - as a company, as leaders and as individuals - depends on our adherence to high ethical standards. Today's compliance environment is highly dynamic and our approach to ethics and compliance must be unwavering, proactive and strategic as regulatory and public expectations continue to evolve. In order to achieve our aspiration, we must maintain a competitive advantage in today's marketplace by living our core values in a manner that reflects our guiding principles of respect, trust and integrity. Endo maintains a Code of Conduct designed to assist employees to make sound and ethical decisions, which is the foundation for how we do business. Acting with respect, trust and integrity is critical to our strategy and is essential to the achievement of our vision. This enables us to earn and keep the trust and confidence of our healthcare customers, patients, regulators and shareholders.

Our Core Values

- Integrity: Uphold an ethical and honest character.
- Customer Focus: Deliver quality products and superior services to those who rely on us.
- Performance Driven: Execute flawlessly to achieve results.
- Collaboration: Unite to empower and build strong working relationships.
- Quality & Continuous Improvement: Fulfill a promise to provide the best.

Code of Conduct

Endo's Code of Conduct (the "Code") governs the Company's internal and external interactions, including with patients, healthcare providers, payors, suppliers, government officials, the healthcare community and shareholders. The Code applies to every person conducting business for Endo and to all Endo locations, subsidiaries and affiliates. Due to local law, some Code provisions may be supplemented by policies or standards to address local requirements.

The Code details, among other things, the role of Endo's Compliance and Business Practices Department (the "Compliance Department"). The Compliance Department, which directly oversees Endo's compliance program, establishes clear rules of business conduct, educates and trains employees, and conducts ongoing monitoring to confirm that the compliance program is operating as intended and to enhance its effectiveness. The Compliance Department also maintains Global and U.S. Compliance Committees comprised of members of the Company's Executive Leadership Team and other senior leaders. The Global and U.S. Compliance Committees oversee, assess and enhance Endo's compliance program as needed across all of Endo's business segments.

Endo is also committed to a culture of openness with clear channels to report potential concerns in a confidential and anonymous manner without fear of retaliation. Endo maintains a 24-hour Ethics Hotline that is operated by an independent third-party vendor and allows callers to report concerns or ask questions confidentially and anonymously. Employees, suppliers, customers and third parties can report concerns or ask questions either by phone or through a website, via our Ethics Hotline. Concerns reported, or questions asked via the Ethics Hotline are routed to the appropriate function or business unit for handling and response. Our Ethics Hotline statistics are reviewed monthly by our Senior Leadership, quarterly by our Compliance Committee of the Board of Directors and periodically by our Global and US Compliance Committees.

The Ethics Hotline is only one of several communication vehicles. Most often, employees discuss such issues directly with their supervisor. This reflects the fact that most day-to-day questions are handled at the local plant or office level with local managers and supervisors. Employees are encouraged to reach out to their Human Resources representative, our Legal department or our Compliance department if they do not feel comfortable going to their direct manager or supervisor.

Annually, all employees complete training on Endo's Code of Conduct. Any employee who violates the Code, Company policy, or applicable laws is subject to disciplinary action up to and included termination. The Code is publicly available at www.endo.com.

Environmental Matters

Endo strives to act in an environmentally responsible way. All employees are responsible for compliance with applicable legal and regulatory requirements on environmental matters.

Endo recognizes that its activities can have an impact on the environment, including as a result of the manner in which Endo sources materials and manufactures products, consumes energy and generates waste. Endo is committed to operating its business in an environmentally responsible manner that seeks to minimize environmental risks and impacts and promotes the safe, efficient and responsible use of global resources. Endo's products and services also support our customers' efforts to make their products more efficient and more environmentally friendly. Specifically, it is Endo's policy to:

- Source our materials, provide our products and services, and manage our facilities in an environmentally responsible manner.
- Minimize material usage, energy consumption and waste generation in the manufacturing of our products for the good of the environment and to minimize overall production costs.
- Research and identify materials and manufacturing methods that minimize impact to the environment through air and water emissions, waste generation, and energy consumption.

Through our regional manufacturing leaders, we engage employees to drive world-class manufacturing and operational excellence and grow our business. All employees are responsible for compliance with applicable legal and regulatory requirements on environmental matters. More broadly, Endo recognizes the relevance and importance of environmental risks and impacts in our wider supply chain.

Endo continues to monitor, review and assess its environmental impact and the outcomes of its environmental policies. The following table shows the data collected for 2018. Key performance indicators covering energy consumption, water consumption, waste generation and recycling have been included because they represent the key areas of Endo's environmental impact. Endo will continue to monitor the key performance indicators below and develop targets for those key performance indicators with the aim of reducing its overall environmental impact.

Key Performance Indicator	Units	Calendar Year 2018
Energy Consumption		
Electricity	Megawatts	69,491
Natural Gas	Centum Cubic Feet	28,231,843
Diesel Fuel	Gallons	206,592
Water Consumption	Gallons	107,822,632
Waste Generation		
Hazardous Waste	Tons	453
Non-Hazardous Incineration	Tons	476
Recycling		
Cardboard, Metal and Plastic	Tons	158

Social and Employee Matters

Endo's culture strives to instill a focus on integrity, patient safety, quality and compliance, while enabling innovation, embracing change, promoting collaboration and rewarding high performance. The company's ability to deliver exceptional and sustainable business results depends upon effectively achieving the desired culture, as well as retaining and attracting diverse enterprise leadership and talent. These critical goals are fundamentally accomplished by developing and deploying robust plans to attract, assess, develop and inspire current and future leaders and employees at all levels of the company, while

providing clear opportunities for professional growth. Endo must also develop and maintain the leadership capacity and workforce with the necessary collective skills and experiences to execute its strategic plan and deliver its operating objectives. Organizational change resulting in unplanned future leadership transitions and/or corporate initiatives, including restructuring actions, could result in talent gaps caused by increased employee turnover. Additionally, organizational disruptions or inability to attract and retain key employees could have a negative effect on Endo's business operations and operating results. The following sections summarize material aspects of Endo's policies relating to social and employee matters and management of the risks outlined above.

Corporate Social Responsibility

Endo values our role in giving back to the patients we serve and the communities where we work. Our corporate giving focuses on the following areas:

Corporate Giving

Employee Matching Gifts - Matching U.S. employee donation dollar for dollar up to $1,000 per employee per calendar year.

Community Support - Endo provides funding to community non-profit organizations endeavoring to provide basic necessities such as food and clothing. We also support organizations providing educational programs to disadvantaged children, programs advancing Science, Technology, Engineering & Math (STEM) education as well as supporting opportunities to assist deserving populations such as seniors or military veterans.

Disease Education - Through unrestricted grants, Endo supports projects which cultivate awareness of the Group's therapeutic areas; seek to improve patient health through disease state education and foster advocacy efforts aimed towards protecting and improving access to quality care for patients.

Disaster Relief - Endo supports humanitarian efforts including recovery from flood or fire through our Disaster Relief program.

Patient Assistance Program

Endo supports patient assistance through third parties, which provide support based on patient need and cover any FDA approved or compendia listed product for specified diseases. These organizations independently develop approval criteria and shield any patient or product specific information from Endo.

Product Donation

In addition to financial support, Endo donates product to help people in need around the globe. All partner organizations are required to adhere to the World Health Organization (WHO) guidelines on product donations. In 2018, Endo donated 476,040 medicines serving approximately 442,000 patients across 65 countries.

Safety, Performance and Quality

Patient health and safety are top priorities. Maintaining the quality of our products and the continued monitoring of their performance is paramount to protecting the safety of patients. We have a responsibility to detect and report adverse events and quality complaints associated with our products, including unfavorable side effects, dosing errors, misuse, malfunctions and concerns about performance or efficacy of a product.

Diversity and Inclusion

At Endo, our ability to achieve exceptional business results and sustainable growth depends upon building and developing a winning mindset and investing in our people. By developing and fully leveraging the collective abilities and strengths of our workforce the company will exceed customers' expectations resulting in meeting our company growth objectives. Achieving these goals requires an engaged organization committed to high performance and operational execution that will drive and deliver exceptional results. The emphasis on diversity and inclusion is a fundamental part of the Endo strategy. We value and respect the diversity of our employees, officers, directors, suppliers, customers and communities.

Progress starts at the top of our organization, where our commitment is realized through leadership examples and communicated throughout the organization. Initiatives to support our goals fall into these categories:

- A company culture that fosters a positive and inclusive environment that values diversity of thought, background and approach.
- Attracting and retaining the best talent across the globe to leverage a variety of perspectives, cultures and experiences.
- Maintaining a workplace where employees are treated with respect and valued for their strengths.
- Fostering a trusting and open work environment where employees can express themselves leading to a high degree of inclusion and engagement.
- Company systems, processes and practices that promote diversity and inclusion resulting in high individual and company productivity and performance.

An important measure of diversity and inclusion is representation. To determine organizational representation and measure progress across the company, certain key metrics and analyses are utilized with respect to geographic considerations:

- Diversity of candidate slates in recruitment activity
- Number of female and male employees and related percentages by organizational level
- Number of employees by race and related percentages by organizational level
- Range of ages (low and high), as well as average and median ages, for each organizational level
- Employee retention rates for females and diverse groups at certain organizational levels.

Anti-Harassment: No Tolerance Environment

Our employees are expected to exhibit the highest standards of professionalism and integrity. Any behavior that constitutes unlawful harassment or discrimination will be thoroughly investigated and not tolerated.

Endo requires that management of each facility implements equal opportunity and no harassment policies in accordance with national, state or provincial law. Employees, temporary employees, visitors and other non-employees are encouraged to immediately report situations of harassment committed by anyone without fear of reprisal, including visitors and other non-employees. Actions taken as a result of an investigation may include discipline and warnings to employees, employee counseling, leadership training, and Equal Employment Opportunity Commission/Harassment training.

We also expect our suppliers to treat their employees with dignity and to maintain workplaces free of discrimination and harassment in all forms.

Employee Development, Training and Education

At Endo, we believe that attracting, developing, motivating and retaining leaders is key to our sustainable and profitable growth. We understand that like customers, our employees and potential employees have choices of where to work, and we must compete for the best talent. We promote excellence in our work environments, performance, teamwork, inclusion, leadership, safety and growth. We encourage community involvement and volunteerism.

Endo supports and facilitates the continued development of its people. Across the organization, employees are encouraged to embrace professional development opportunities and our leaders monitor the progress of the growth of their respective teams. The company also has well established succession planning and talent review processes, focused on the development and growth of our people with an emphasis on advancing diverse talent. The Executive Leadership Team, as well as business unit and functional leadership, discuss top talent regularly during their scheduled meetings to confirm that they are up-to-date on progress and gaps. To build a robust talent pipeline, organizational and individual development plans are used to accelerate the growth of high-potential employees by distinguishing key strengths and areas for growth, and identifying key events and experiences needed for development.

High performance at Endo is an outcome of an individual embracing the company's core values and doing things the right way. Performance is enhanced by a person's aspiration and ability to learn, adapt, and grow throughout an individual's career. At Endo, the emphasis is on the value of on-the-job, real-time learning that enables a person to meet the demands of challenging and changing work. Our approach to learning focuses on reinforcing key principles that are designed to support an individual's effectiveness in his or her current job, and in future situations.

Endo is committed to providing leadership and learning opportunities for talent at all levels in their careers. Training is provided in a number of formats to accommodate the learner's style and pace, location and technological knowledge and

access. Endo offers programmatic and individual development courses and opportunities across the organization in a variety of delivery methods.

Employee Safety & Privacy

Endo is committed to maintaining a work environment free from any substance that could impair our ability to safely and professionally execute our job responsibilities. Violence in the workplace will not be tolerated.

The following table sets out key performance indicators related to the safety of our employees:

Key Performance Indicator	Units	Calendar Year 2018
Safety		
OSHA Injury Rate	Per 100 Employees	1.2
Days Away, Restricted and Transferred	Days	23.5
Recordable Injuries	Number	29
Total Manhours Site Worked	Hours	4,831,760
Number of Employees	Employees	2,124

We have established a Comprehensive Compliance Program (CCP) for our U.S. based operating companies, which includes procedures to identify potential violations and to address inappropriate conduct as necessary. In addition, Endo assesses its CCP on an ongoing basis and makes enhancements as necessary.

Changes in healthcare will increasingly require us as well as our customers to utilize personal information. As a global company, our strategy and daily operations necessitate the collection, use and, at times, sharing of personal information about patients as well as our customers, shareholders and employees as permitted by local laws. We have safeguards to protect personal data, and we limit data access to employees who need it for business purposes. We follow local data protection and privacy laws.

Endo continues to monitor, review and assess the outcomes of its policies on social and employee matters to confirm that they are having the desired impact.

Human Rights

Endo is committed to respecting human rights. At Endo, we believe that it is our responsibility to respect and uphold the human rights of our people and any other individuals we are in contact with across the globe. We believe this is evident in all our policies and practices, including HR, Safety and Procurement.

Endo enforces the following specific policies with respect to the protection of and respect for our global employee workforce:

- General conduct policy with rules pertaining to an employee's responsibilities and conduct.
- Complies with minimum legal working age requirements.
- Sets work hours to comply with local law.
- Complies with applicable wage laws, regulations, and relevant collective bargaining agreements, including those relating to minimum wages, overtime hours and legally mandated benefits.
- Maintains workplaces free of harassment and abuse.
- Recruits, hires, trains and promotes employees without regard to their race, color, religion, gender, age, national origin, citizenship, caste, marital status, sexual orientation, gender identity, genetic information, disability, veteran status or other protected characteristic.
- Respects employees' voluntary freedom of association, including the right to organize and bargain collectively.

Our global supplier standards also require our suppliers to treat workers with dignity and follow similar policies as outlined above for the supplier's employee workforce.

As discussed above, Endo employees are trained on our Code of Conduct and educated on how to report potential ethical violations or claims of harassment or discrimination without fear of retaliation. All complaints of alleged human rights

violations, ethical concerns, or claims of harassment or discrimination are thoroughly investigated and appropriate disciplinary action is taken if warranted.

Bribery and Corruption

Endo provides annual training to its employees on a variety of anti-corruption and related matters, including the Foreign Corrupt Practices Act, anti-bribery, conflicts of interest, statements from our Code of Conduct and our Code of Conduct more broadly.

As regulators, payers, or purchasers of our products, government officials are integral to our business. Healthcare professionals who are public employees may be considered government officials in many countries. Through our research and development, regulatory, manufacturing and import/export activities, we may interact with government officials or entities that are state owned. Payments, gifts or services should not be given to government employees or healthcare providers that are intended to or appear to influence their actions. In short, Endo does not permit bribery of any kind.

Disclaimer: The information in Endo's Non-Financial Statement is shared based on the best available data at publication. In some cases, data is estimated. Endo cautions that our statements with respect to current and future potential implications of corporate social responsibility and sustainability topics are subject to numerous important risks, uncertainties, assumptions and other factors, some of which are beyond Endo's control, which could cause Endo's actual results and business implications to different materially from those expressed or implied by the information in this report.

Subsidiary Companies and Branches

Information regarding subsidiary undertakings and associates is provided in Note 28. Subsidiaries of the accompanying Consolidated Financial Statements included in this report. The Group does not operate any branches outside of the State.

Going Concern

The Board has formed a judgment at the time of approving the financial statements that there is a reasonable expectation that the Group and the Company have adequate resources to continue in operational existence for the foreseeable future. In arriving at this conclusion, the Board has taken account of current and anticipated trading performance, together with the current and anticipated levels of net debt and the availability of the committed borrowing facilities. For this reason, the going concern basis continues to be adopted in the preparation of the Group and the Company financial statements.

Disclosure of Information to the Auditor

For the purposes of section 330 of the Companies Act 2014, each of the persons who are Directors at the date of approval of this report individually confirm that:

- In so far as they are aware, there is no relevant audit information, as defined in section 330, of which the Group's auditor is unaware; and
- That they have taken all the steps that they ought to have taken as a Director in order to make themselves aware of any relevant audit information and to establish that the Group's auditor is aware of such information.

Audit Committee

In accordance with Section 167 of the Companies Act 2014, Endo has an audit committee, which meets the requirements of the Companies Act.

Annual Compliance Statement of Endo International Plc (the Company)

The Directors acknowledge that they are responsible for securing compliance by the Company with its Relevant Obligations as defined in Section 225 of the Companies Act, 2014 (the Relevant Obligations).

The Directors confirm that they have drawn up and adopted a compliance policy statement setting out the Company's policies that, in the Directors' opinion, are appropriate to the Company respecting compliance with its Relevant Obligations.

The Directors further confirm the Company has put in place appropriate arrangements or structures that are, in the Directors' opinion, designed to secure material compliance with its Relevant Obligations including reliance on the advice of persons employed by the Company and external legal and tax advisers as considered appropriate from time to time and that they have reviewed the effectiveness of these arrangements or structures during the financial year to which this report relates.

Annual General Meeting

The Annual General Meeting of the Group will take place at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland, on June 11, 2019.

Statutory Auditors

The statutory auditors, PricewaterhouseCoopers (PwC) have indicated their willingness to continue in office, and a resolution that they be reappointed will be proposed at the Annual General Meeting.

On behalf of the Directors

/s/ Roger H. Kimmel	/s/ Paul Campanelli
Roger H. Kimmel	Paul Campanelli
Chairman	*Director*

April 24, 2019

ENDO INTERNATIONAL PLC
STATEMENT OF DIRECTORS' RESPONSIBILITIES

The directors are responsible for preparing the directors' report and the group and company financial statements in accordance with Irish law.

Irish law requires the directors to prepare group and company financial statements for each financial year giving a true and fair view of the group and company's assets, liabilities and financial position at the end of the financial year and the profit or loss of the group and company for the financial year. Under that law the directors have prepared the financial statements in accordance with Irish Generally Accepted Accounting Practice (accounting standards issued by the UK Financial Reporting Council, including Financial Reporting Standard 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* and Irish law).

Under Irish law, the directors shall not approve the group and company financial statements unless they are satisfied that they give a true and fair view of the group and company's assets, liabilities and financial position as at the end of the financial year and the profit or loss of the group and company for the financial year.

In preparing these financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and estimates that are reasonable and prudent;
- state whether the financial statements have been prepared in accordance with applicable accounting standards and identify the standards in question, subject to any material departures from those standards being disclosed and explained in the notes to the financial statements; and
- prepare the financial statements on a going concern basis unless it is inappropriate to presume that the group and company will continue in business.

The directors are responsible for keeping adequate accounting records that are sufficient to:

- correctly record and explain the transactions of the group and company;
- enable, at any time, the assets, liabilities, financial position and profit or loss of the group and company to be determined with reasonable accuracy; and
- enable the directors to ensure that the financial statements comply with the Companies Act 2014 and enable those financial statements to be audited.

The directors are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

pwc

Independent auditors' report to the members of Endo International plc

Report on the audit of the financial statements

Opinion

In our opinion:

- Endo International plc's Consolidated financial statements and Company financial statements (the "financial statements") give a true and fair view of the Group's and the Company's assets, liabilities and financial position as at 31 December 2018 and of the Group's loss and cash flows for the year then ended;
- the Consolidated financial statements have been properly prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP"), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of consolidated financial statements does not contravene any provision of Part 6 of the Companies Act 2014;
- the Company financial statements have been properly prepared in accordance with Generally Accepted Accounting Practice in Ireland (accounting standards issued by the Financial Reporting Council of the UK, including Financial Reporting Standard 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" and Irish law); and
- the financial statements have been properly prepared in accordance with the requirements of the Companies Act 2014.

We have audited the financial statements, included within the Directors' Report and Financial Statements (the "Annual Report"), which comprise:

- the Consolidated Balance Sheet as at 31 December 2018;
- the Company Balance Sheet as at 31 December 2018;
- the Consolidated Profit and Loss Account and the Consolidated Statement of Comprehensive Loss for the year then ended;
- the Consolidated Statement of Cash Flows for the year then ended;
- the Consolidated Reconciliation of Shareholders' Funds for the year then ended;
- the Company Reconciliation of Shareholders' Funds for the year then ended; and
- the Notes to the Consolidated Financial Statements and the Notes to the Company Financial Statements, which include a description of the significant accounting policies.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) ("ISAs (Ireland)") and applicable law. Our responsibilities under ISAs (Ireland) are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Independence

We remained independent of the group in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, which includes IAASA's Ethical Standard as applicable to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

Our audit approach

Overview

Materiality

- $33 million (2017: $30 million) - Consolidated financial statements
- Based on approximately 2.5% of EBITDA from continuing operations, adjusted for asset impairment charges, changes in the fair value of contingent consideration and separation benefits and other restructuring charges.
- $20 million (2017: $20.5 million) - Company financial statements
- Based on approximately 1% of total assets.

Audit scope

- We performed audit procedures over four reporting components selected across the Group's reportable segments. We paid particular attention to these components due to their size or characteristics and to ensure appropriate audit coverage. Full scope audits were performed on three components and specified procedures were performed on one component.
- Taken together, through the performance of full scope audits and specified audit procedures, we obtained coverage of 95% of Group revenues, 96% of EBITDA from continuing operations, adjusted for asset impairment charges, changes in the fair value of contingent consideration and separation benefits and other restructuring charges and 97% of Group total assets.

Key audit matters

- Sales Deduction Provisions.
- Valuation of Goodwill.
- Valuation of Definite-Lived and Indefinite-Lived Intangible Assets.

The scope of our audit

As part of designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we looked at where the directors made subjective judgements, for example in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits we also addressed the risk of management override of internal controls, including evaluating whether there was evidence of bias by the directors that represented a risk of material misstatement due to fraud.

Key audit matters

Key audit matters are those matters that, in the auditors' professional judgement, were of most significance in the audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by the auditors, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters, and any comments we make on the results of our procedures thereon, were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. This is not a complete list of all risks identified by our audit.

Key audit matter	*How our audit addressed the key audit matter*
Sales Deduction Provisions *Refer to Notes 2 and 22 to the consolidated financial statements.* The Group makes sales to various customers in the United States that fall under certain commercial and governmental mandated contracts and reimbursement arrangements. These programs and arrangements result in deductions to gross sales and give rise to obligations for the Group to provide direct and indirect customers with rebates, discounts, allowances, and the right of product return, for which unsettled amounts are recorded as estimated sales deduction provisions. As of December 31, 2018, the Group has recorded a reserve of $772.3 million for sales deduction provisions. $387.5 million is classified as a reduction of Debtors and $384.8 million is classified as Provision for liabilities within the Consolidated Balance Sheet. Based on our knowledge of these programs, we believe the most significant and complex are Medicaid and Medicare, which are included within the U.S. Branded - Specialty & Established Pharmaceuticals Segment and Wholesaler Chargebacks, Rebates, and Medicaid which are included in the U.S. Branded - Sterile Injectables and U.S. Generic Pharmaceuticals Reporting Segments. These programs are complex and establishing an appropriate provision requires significant judgement and estimation based on historical experience of payor utilisation, estimated customer stock levels, current contract sales terms with both direct and indirect customers, estimated future trends and other competitive factors of the Group.	We tested controls over the valuation of sales deduction provisions, which included control activities designed to: • assess the reasonableness of assumptions used relating to forecasted discounts, payor utilisation, and wholesaler and retailer inventory levels; • assess the completeness and accuracy of payment amounts recorded as reductions to the provisions; • determine the mathematical accuracy of the provisions; and • address the correct balance sheet classification of the provisions between liability and reduction of accounts receivable. We developed an independent estimate for these provisions at December 31, 2018 using historical payment information, known contractual pricing and third party data, where available. We compared this expectation to the provisions established by the Group. We considered the historical accuracy of the Group's estimates in previous years by comparing historical reserves to settlements processed during the year. We tested a sample of settlements to both direct and indirect customers to determine that the settlements were made in accordance with agreed terms.
Valuation of Goodwill *Refer to Notes 2 and 9 to the consolidated financial statements.* The Group has material goodwill for the U.S. Branded - Specialty & Established Pharmaceuticals, U.S. Branded - Sterile Injectables, U.S. Generics and International reporting units. Goodwill is required to be tested for impairment annually or when triggering events occur. The Group conducts an impairment test during the fourth fiscal quarter or more frequently if events or changes in circumstances indicate the carrying value of goodwill might be impaired. The impairment reviews performed by the Group contain a number of significant judgements and estimates. The most significant judgements and estimates include estimates of future operating performance, including future sales, long-term growth rates, operating margins, the probability of success of products under development and the discount rates applied to the estimated future cash flows. As described within Note 9 to the consolidated financial statements, the Group recognised impairments to goodwill of $680 million during the year ended December 31, 2018. Of the $680 million total goodwill impairment charge, $391 million was recorded as a result of the impairment test carried out due to the Group's change in segments during the year, which resulted in a change in the Group's reporting units. Subsequent to the change in segments the new U.S. Generic Pharmaceuticals reporting unit's carrying amount exceeded its estimated fair value resulting in a goodwill impairment charge of $391 million. The balance of the impairment charge of $289 million was recorded following the Group's annual goodwill impairment test. These impairment tests are significant to our audit because the estimates of fair value for each reporting unit are complex,	We tested controls over the valuation of goodwill, which included control activities designed to: • address the identification of triggering events to determine whether an impairment test was needed, in addition to the annual test; • address the proper determination of reporting units and the accurate calculation of each reporting unit's net book value; • assess the reasonableness of estimated future cash flows, discount rates, long term growth rates and other assumptions used to estimate fair value. We assessed the Group's determination of reporting units, which is the level the goodwill impairment test is performed at, by considering whether the reporting units are at the operating segment level or one level below. We evaluated the change in reportable segments during the year, including considering the information provided to the Chief Operating Decision Maker. We tested management's process for the allocation of assets, including goodwill, other assets and liabilities to reporting units and evaluated the methods used by management in developing the fair value measurements. We evaluated whether there were any additional events or circumstances indicating that carrying amount of goodwill may exceed its fair value and therefore requiring goodwill impairment tests in addition to the annual test. We assessed the reasonableness of estimates of future revenue and operating margins from product sales and the probability of success for products under development by comparing relevant assumptions to historical performance and industry

Key audit matter	*How our audit addressed the key audit matter*
require management judgement, and the results significantly impact the Group's results of operations and financial position.	and economic forecasts, as appropriate. Our procedures also included the involvement of our internal specialists with skills and knowledge in valuation, to assist us in evaluating the reasonableness of significant assumptions, including the discount rate utilised in the discounted cash flow analysis and long term growth rates used by management. This included comparing these assumptions to external data. We also tested the mathematical accuracy of the valuation models and considered the appropriateness of these valuation models.
Valuation of Definite-Lived and Indefinite-Lived Intangible Assets *Refer to Notes 2 and 9 to the consolidated financial statements.* The Group has material definite-lived intangible assets which are mainly comprised of developed technology, and indefinite-lived intangible assets which are mainly comprised of in-process research and development assets. Definite-lived intangibles are required to be tested for impairment when events occur that indicate long-lived assets may not be recoverable ("triggering events"). Indefinite-lived intangible assets are required to be tested for impairment annually or when triggering events occur. In fiscal 2018, the Group concluded it had a triggering events requiring assessment of impairment for certain definite and indefinite lived intangible assets. As described within Note 9 to the consolidated financial statements, the Group recognised impairments to definite-lived intangible assets of $142.5 million and indefinite-lived intangible assets of $87.9 million respectively during the year ended December 31, 2018. The charges relate primarily to certain in-process research and development and developed technology intangible assets that were tested for impairment following changes in market conditions and certain other factors impacting recoverability. The impairment reviews performed by the Group contain a number of significant judgements and estimates. The most significant judgements and estimates include estimates of future operating performance, including future sales, long-term growth rates, operating margins, the probability of success of products under development and the discount rates applied to the estimated future cash flows. These impairment tests are significant to our audit because the estimates of fair value for each intangible asset are complex, require management judgement, and the results significantly impact the Group's results of operations and financial position.	We tested controls over the valuation of definite-lived and indefinite-lived intangible assets, which included control activities designed to: • address the identification of triggering events to determine whether an impairment test was needed; • assess the appropriateness of assumptions used in estimating future cash flows, discount rates and probability of success of products under development. We evaluated whether there were any additional events or circumstances indicating that intangible assets may be impaired. We assessed the reasonableness of estimates of future revenue and operating margin from product sales and the probability of success for products under development by comparing relevant assumptions to historical performance and industry and economic forecasts, as appropriate. Our procedures also included the involvement of our internal specialists with skills and knowledge in valuation to assist us in evaluating the reasonableness of significant assumptions, including the discount rate used in the discounted cash flow analysis by management. This included comparing these assumptions to external data, where appropriate. We also tested the mathematical accuracy of the valuation models and considered the appropriateness of these valuation models.

How we tailored the audit scope

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole, taking into account the structure of the group, the accounting processes and controls, and the industry in which the group operates.

The consolidated financial statements are a consolidation of four reportable segments (U.S. Generic Pharmaceuticals, U.S. Branded - Specialty & Established Pharmaceuticals, U.S. Branded - Sterile Injectables and International Pharmaceuticals) consisting of over 90 legal entities. Reporting components are structured by individual legal entities or groupings of legal entities depending on their management team and structure.

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole, taking into account the structure of the Group, the accounting processes and controls and the industry in which the Group operates.

In determining our audit scope we focused on individual reporting components and determined the type of work that needed to be performed at the reporting components by us, as the Irish group engagement team, PwC US as the global engagement team, or other component auditors within other PwC network firms. Where the work was performed by PwC US and other component auditors, we determined the level of involvement we needed to have in the audit work of those reporting components to be able to conclude whether sufficient appropriate audit evidence had been obtained as a basis for our opinion on the financial statements as a whole.

Through the performance of full scope audits and specified audit procedures, we obtained coverage of 95% of Group revenues, 96% of EBITDA from continuing operations, adjusted for asset impairment charges, changes in the fair value of contingent consideration and separation benefits and other restructuring charges and 97% of Group total assets. Included in the coverage were certain reporting components where specific audit procedures on consolidated balances were performed. This, together with additional procedures performed at group level, gave us the evidence we needed for our opinion on the financial statements as a whole.

Materiality

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

Based on our professional judgement, we determined materiality for the financial statements as a whole as follows:

	Consolidated financial statements	*Company financial statements*
Overall materiality	$33 million (2017: $30 million).	$20 million (2017: $20.5 million).
How we determined it	2.5% of EBITDA, adjusted for asset impairment charges, changes in the fair value of contingent consideration and separation benefits and other restructuring charges.	1% of total assets.
Rationale for benchmark applied	We believe that EBITDA from continuing operations, adjusted for asset impairment charges, changes in the fair value of contingent consideration and separation benefits and other restructuring charges provides us with a consistent year on year basis for determining materiality and is the most relevant metric for the users of the financial statements.	As the Company is a holding company we believe that total assets are the most appropriate benchmark to calculate materiality.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above $1.5 million (group audit) (2017: $1.5 million) and $1 million (company audit) (2017: $1 million) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

Conclusions relating to going concern

We have nothing to report in respect of the following matters in relation to which ISAs (Ireland) require us to report to you where:

- the directors' use of the going concern basis of accounting in the preparation of the financial statements is not appropriate; or
- the directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the group's or the company's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

However, because not all future events or conditions can be predicted, this statement is not a guarantee as to the group's or the company's ability to continue as a going concern.

Reporting on other information

The other information comprises all of the information in the Directors' Report and Financial Statements other than the financial statements and our auditors' report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except to the extent otherwise explicitly stated in this report, any form of assurance thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the

audit, or otherwise appears to be materially misstated. If we identify an apparent material inconsistency or material misstatement, we are required to perform procedures to conclude whether there is a material misstatement of the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report based on these responsibilities.

With respect to the Directors' Report, we also considered whether the disclosures required by the Companies Act 2014 (excluding the information included in the "Non Financial Statement" as defined by that Act on which we are not required to report) have been included.

Based on the responsibilities described above and our work undertaken in the course of the audit, ISAs (Ireland) and the Companies Act 2014 require us to also report certain opinions and matters as described below:

- In our opinion, based on the work undertaken in the course of the audit, the information given in the Directors' Report (excluding the information included in the "Non Financial Statement" on which we are not required to report) for the year ended 31 December 2018 is consistent with the financial statements and has been prepared in accordance with the applicable legal requirements.
- Based on our knowledge and understanding of the group and company and their environment obtained in the course of the audit, we have not identified any material misstatements in the Directors' Report (excluding the information included in the "Non Financial Statement" on which we are not required to report).

Responsibilities for the financial statements and the audit

Responsibilities of the directors for the financial statements

As explained more fully in the Statement of Directors' Responsibilities set out on page 70, the directors are responsible for the preparation of the financial statements in accordance with the applicable framework and for being satisfied that they give a true and fair view.

The directors are also responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the group's and the company's ability to continue as a going concern, disclosing as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the group or the company or to cease operations, or have no realistic alternative but to do so.

Auditors' responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on the IAASA website at:

https://www.iaasa.ie/getmedia/b2389013-1cf6-458b-9b8f-a98202dc9c3a/Description_of_auditors_responsibilities_for_audit.pdf

This description forms part of our auditors' report.

Use of this report

This report, including the opinions, has been prepared for and only for the company's members as a body in accordance with section 391 of the Companies Act 2014 and for no other purpose. We do not, in giving these opinions, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

Other required reporting

Companies Act 2014 opinions on other matters

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the Company were sufficient to permit the Company financial statements to be readily and properly audited.
- The Company Balance Sheet is in agreement with the accounting records.

Companies Act 2014 exception reporting

Directors' remuneration and transactions

Under the Companies Act 2014 we are required to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by sections 305 to 312 of that Act have not been made. We have no exceptions to report arising from this responsibility.

Gareth Hynes
for and on behalf of PricewaterhouseCoopers
Chartered Accountants and Statutory Audit Firm
Dublin
24 April 2019

ENDO INTERNATIONAL PLC
CONSOLIDATED PROFIT AND LOSS ACCOUNT
YEARS ENDED DECEMBER 31, 2018 AND 2017
(In thousands, except per share data)

	Note	2018	2017
TURNOVER	5	$ 2,947,078	$ 3,468,858
Cost of sales	2,5	1,631,682	2,228,530
GROSS PROFIT		1,315,396	1,240,328
Selling, general and administrative expenses		646,037	629,874
Research and development expenses		185,826	172,067
Litigation-related and other contingency expenses	13	13,809	185,990
Asset impairment charges	8,9	916,939	1,154,376
Acquisition-related and integration items	5	21,914	58,086
OPERATING LOSS		$ (469,129)	$ (960,065)
INTEREST RECEIVABLE AND SIMILAR INCOME	12	(13,194)	(6,466)
INTEREST PAYABLE AND SIMILAR CHARGES	12	534,850	494,694
LOSS ON EXTINGUISHMENT OF DEBT	12	—	51,734
OTHER INCOME, NET	17	(51,953)	(17,023)
LOSS FROM CONTINUING OPERATIONS BEFORE TAXATION		$ (938,832)	$ (1,483,004)
TAX EXPENSE (BENEFIT) FROM CONTINUING OPERATIONS	18	22,935	(250,293)
LOSS FROM CONTINUING OPERATIONS		$ (961,767)	$ (1,232,711)
DISCONTINUED OPERATIONS, NET OF TAX	3	(69,702)	(802,722)
LOSS FOR THE FINANCIAL YEAR		$ (1,031,469)	$ (2,035,433)
LOSS PER SHARE - BASIC:			
Continuing operations		$ (4.29)	$ (5.52)
Discontinued operations		(0.32)	(3.60)
Basic		$ (4.61)	$ (9.12)
LOSS PER SHARE - DILUTED:			
Continuing operations		$ (4.29)	$ (5.52)
Discontinued operations		(0.32)	(3.60)
Diluted		$ (4.61)	$ (9.12)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:			
Basic	19	223,960	223,198
Diluted	19	223,960	223,198

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS
YEARS ENDED DECEMBER 31, 2018 AND 2017
(In thousands)

	Note	2018	2017
LOSS FOR THE FINANCIAL YEAR		$ (1,031,469)	$ (2,035,433)
Net unrealized loss on securities	7,14	—	(515)
Foreign currency translation (loss) gain	14	(19,408)	144,128
TOTAL OTHER COMPREHENSIVE LOSS		$ (1,050,877)	$ (1,891,820)

ENDO INTERNATIONAL PLC
CONSOLIDATED BALANCE SHEET
DECEMBER 31, 2018 AND 2017
(In thousands)

	Note	December 31, 2018	December 31, 2017
ASSETS			
Non-current Assets			
Investments	6	$ 738	$ 1,456
Tangible assets	8	498,892	523,971
Intangible assets-Goodwill	9	3,764,636	4,450,082
Intangible assets-Other	9	3,457,306	4,317,684
Other	21	67,671	71,310
Current Assets			
Stock	7	322,179	391,437
Debtors	21	616,490	572,582
Cash at bank and in-hand		1,149,113	986,605
Restricted cash		305,368	320,453
TOTAL ASSETS		$ 10,182,393	$ 11,635,580
EQUITY AND LIABILITIES			
Capital and Reserves			
Called up share capital presented as equity	15	$ 68	$ 70
Share premium account	15	6,140,505	6,140,434
Other reserves		(9,566,752)	(9,611,913)
Profit and loss account		2,927,896	3,956,289
Total equity shareholders' funds		$ (498,283)	$ 484,880
Creditors: amounts falling due within one year			
Debenture loans-current portion	12	$ 34,150	$ 34,205
Trade and other creditors	22	1,544,655	1,642,190
		$ 1,578,805	$ 1,676,395
Creditors: amounts falling due after more than one year			
Debenture loans	12	$ 8,224,269	$ 8,242,032
Trade and other creditors	22	376,122	567,860
Total for creditors: amounts falling due after more than one year		$ 8,600,391	$ 8,809,892
Provision for liabilities	22	$ 501,480	$ 664,413
TOTAL EQUITY AND LIABILITIES		$ 10,182,393	$ 11,635,580

The accompanying notes are an integral part of these Consolidated Financial Statements.
The Consolidated Financial Statements were approved by the Board of Directors on April 24, 2019 and signed on its behalf by:

/s/ Roger H. Kimmel	/s/ Paul Campanelli
Roger H. Kimmel	Paul Campanelli
Chairman	*Director*

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENT OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2018 AND 2017
(In thousands)

	2018	2017
OPERATING ACTIVITIES:		
Consolidated net loss	$ (1,031,469)	$ (2,035,433)
Adjustments to reconcile consolidated net loss to Net cash provided by operating activities:		
Depreciation and amortization	723,707	983,765
Stock step-up	261	390
Share-based compensation	54,071	50,149
Amortization of debt issuance costs and discount	20,514	22,694
Deferred income taxes	5,557	(156,129)
Change in fair value of contingent consideration	19,910	49,949
Loss on extinguishment of debt	—	51,734
Asset impairment charges	916,939	1,154,376
Gain on sale of business and other assets	(45,155)	(13,809)
Changes in assets and liabilities which (used) provided cash:		
Debtors	17,090	484,710
Stock	67,269	147,189
Prepaid and other assets	(12,797)	5,345
Accounts payable, accrued expenses and other liabilities	(425,336)	(87,944)
Income taxes payable/receivable	(43,291)	(103,001)
Net cash provided by operating activities	$ 267,270	$ 553,985
INVESTING ACTIVITIES:		
Purchases of tangible fixed assets	(83,398)	(125,654)
Capitalized interest payments	(3,549)	—
Decrease in notes receivable	—	7,000
Product acquisition costs and license fees	(3,000)	—
Proceeds from sale of business and other assets, net	70,369	223,237
Other investing activities	1,678	—
Net cash provided by (used in) investing activities	$ (17,900)	$ 104,583
FINANCING ACTIVITIES:		
Proceeds from issuance of notes	—	300,000
Proceeds from issuance of term loans	—	3,415,000
Principal payments on term loans	(34,150)	(3,730,951)
Principal payments on other indebtedness	(5,222)	(6,154)
Deferred financing fees	—	(57,773)
Payments for contingent consideration	(37,758)	(85,037)
Payments of tax withholding for restricted shares	(5,375)	(2,078)
Exercise of options	933	—
Net cash (used in) provided by financing activities	$ (81,572)	$ (166,993)
Effect of foreign exchange rate	(1,975)	2,515
Movement in cash held for sale	—	11,744
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS	$ 165,823	$ 505,834
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, BEGINNING OF PERIOD	1,311,014	805,180
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, END OF PERIOD	$ 1,476,837	$ 1,311,014
SUPPLEMENTAL INFORMATION:		

	2018	2017
Cash paid for interest	$ 515,042	$ 467,017
Cash paid for income taxes	$ 17,639	$ 28,675
Cash received from U.S. Federal tax refunds	$ —	$ 29,825
Cash paid into Qualified Settlement Funds for mesh legal settlements	$ 336,648	$ 668,306
Cash paid out of Qualified Settlement Funds for mesh legal settlements	$ 353,032	$ 632,176
Other cash distributions for mesh legal settlements	$ 25,222	$ 19,243

ENDO INTERNATIONAL PLC
CONSOLIDATED RECONCILIATION OF SHAREHOLDERS' FUNDS
YEARS ENDED DECEMBER 31, 2018 AND 2017
(In thousands)

	Endo International plc Shareholders				
	Share Capital	Share Premium	Profit and Loss Account	Other Reserves	Total
BALANCE, DECEMBER 31, 2016	$ 64	$ 6,140,580	$ 6,364,547	$ (9,803,602)	$ 2,701,589
Effect of adopting ASU 2016-16 (NOTE 18)	—	—	(372,825)	—	(372,825)
BALANCE, January 1, 2017	$ 64	$ 6,140,580	$ 5,991,722	$ (9,803,602)	$ 2,328,764
Net loss	—	—	(2,035,433)	—	(2,035,433)
Other comprehensive income	—	—	—	143,613	143,613
Compensation related to share-based awards	—	—	—	50,149	50,149
Tax withholding for restricted shares	—	—	—	(2,078)	(2,078)
Other	6	(146)	—	5	(135)
BALANCE, DECEMBER 31, 2017	$ 70	$ 6,140,434	$ 3,956,289	$ (9,611,913)	$ 484,880
Effect of adopting ASC 606 (NOTE 2)	—	—	3,076	—	3,076
BALANCE, January 1, 2017	$ 70	$ 6,140,434	$ 3,959,365	$ (9,611,913)	$ 487,956
Net loss	—	—	(1,031,469)	—	(1,031,469)
Other comprehensive loss	—	—	—	(19,408)	(19,408)
Compensation related to share-based awards	—	—	—	54,071	54,071
Exercise of options	—	—	—	933	933
LTCI modification (NOTE 16)	—	—	—	14,936	14,936
Tax withholding for restricted shares	—	—	—	(5,375)	(5,375)
Other	(2)	71	—	4	73
BALANCE, DECEMBER 31, 2017	$ 68	$ 6,140,505	$ 2,927,896	$ (9,566,752)	$ (498,283)

NOTE 1. DESCRIPTION OF BUSINESS

Endo International plc is an Ireland-domiciled, global specialty pharmaceutical company focused on generic and branded pharmaceuticals. We aim to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of generic and branded drugs to meet patients' needs. Unless otherwise indicated or required by the context, references throughout to "Endo," the "Group," "we," "our" or "us" refer to financial information and transactions of Endo International plc and its subsidiaries. The accompanying Consolidated Financial Statements of Endo International plc and its subsidiaries have been prepared in accordance with U.S. GAAP.

NOTE 2. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING PRINCIPLES

The directors have elected to prepare the consolidated financial statements of Endo International plc in accordance with applicable Irish law and accounting principles generally accepted in the United States of America (U.S. GAAP), as defined in Section 279 (1) of Part 6 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Acts or of any regulations made thereunder.

The separate financial statements of the Group have been prepared in accordance with the Companies Act 2014 and Financial Reporting Standard 102. The financial statements are presented in U.S. dollars.

The significant accounting policies adopted by the Group are as follows:

Consolidation and Basis of Presentation. The Consolidated Financial Statements include the accounts of wholly owned subsidiaries after the elimination of intercompany accounts and transactions.

Reclassifications. Certain prior period amounts have been reclassified to conform to the current period presentation.

Use of Estimates. The preparation of our Consolidated Financial Statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts and disclosures in our Consolidated Financial Statements, including the notes thereto, and elsewhere in this report. For example, we are required to make significant estimates and assumptions related to turnover recognition, including sales deductions, financial instruments, long-lived assets, goodwill, other intangibles, income taxes, contingencies and share-based compensation, among others. Some of these estimates can be subjective and complex. Although we believe that our estimates and assumptions are reasonable, there may be other reasonable estimates or assumptions that differ significantly from ours. Further, our estimates and assumptions are based upon information available at the time they were made. Actual results may differ significantly from our estimates.

We regularly evaluate our estimates and assumptions using historical experience and other factors, including the economic environment. As future events and their effects cannot be determined with precision, our estimates and assumptions may prove to be incomplete or inaccurate, or unanticipated events and circumstances may occur that might cause us to change those estimates and assumptions. Market conditions, such as illiquid credit markets, volatile equity markets, dramatic fluctuations in foreign currency rates and economic downturn, can increase the uncertainty already inherent in our estimates and assumptions. We also are subject to other risks and uncertainties that may cause actual results to differ from estimated amounts, such as changes in the healthcare environment, competition, litigation, legislation and regulations. We adjust our estimates and assumptions when facts and circumstances indicate the need for change. Those changes generally will be reflected in our Consolidated Financial Statements on a prospective basis.

Customer, Product and Supplier Concentration. We primarily sell our generic and branded pharmaceuticals to wholesalers, retail drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, hospitals and government agencies. Our wholesalers and distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies and managed health care organizations. Customers in the managed health care market include health maintenance organizations, nursing homes, hospitals, clinics, pharmacy benefit management companies and mail order customers. Total turnover from direct customers that accounted for 10% or more of our total consolidated turnover during the years ended December 31, 2018 and 2017 are as follows:

	2018	2017
AmerisourceBergen Corporation	32%	25%
McKesson Corporation	27%	25%
Cardinal Health, Inc.	26%	25%

Turnover from these customers are included within each of our segments.

VASOSTRICT® accounted for 15% and 12% of our 2018 and 2017 total turnover, respectively. No other products accounted for 10% or more of our total turnover during the years ended December 31, 2018 or 2017.

We have agreements with certain third parties for the manufacture, supply and processing of certain of our existing pharmaceutical products. See Note 13. Commitments and Contingencies for information on material manufacturing, supply and other service agreements.

We are subject to risks and uncertainties associated with these concentrations that could have a material adverse effect on our financial position and results of operations in future periods, including in the near term.

Turnover Recognition and Sales Deductions. The Group adopted *Accounting Standards Codification Topic 606, Revenue from Contracts with Customers* (ASC 606) on January 1, 2018 using the modified retrospective method for all turnover-generating contracts, including modifications thereto, that were not completed contracts at the date of adoption. ASC 606 applies to contracts with commercial substance that establish the payment terms and each party's rights regarding the goods or services to be transferred, to the extent collection of substantially all of the related consideration is probable. Under ASC 606, we recognize turnover for contracts meeting these criteria when (or as) we satisfy our performance obligations for such contracts by transferring control of the underlying promised goods or services to our customers. The amount of turnover we recognize reflects our estimate of the consideration we expect to be entitled to receive, subject to certain constraints, in exchange for such goods or services. This amount is referred to as the transaction price.

Our turnover consists almost entirely of sales of our pharmaceutical products to customers, whereby we ship products to a customer pursuant to a purchase order. For contracts such as these, turnover is recognized when our contractual performance obligations have been fulfilled and control has been transferred to the customer pursuant to the contract's terms, which is generally upon delivery to the customer. The amount of turnover we recognize is equal to the fixed amount of the transaction price, adjusted for our estimates of a number of significant variable components including, but not limited to, estimates for chargebacks, rebates, sales incentives and allowances, DSA and other fees for services, returns and allowances, which we collectively refer to as sales deductions. The Group utilizes the expected value method when estimating the amount of variable consideration to include in the transaction price with respect to each of the foregoing variable components and the most likely amount method when estimating the amount of variable consideration to include in the transaction price with respect to future potential milestone payments that do not qualify for the sales- and usage-based royalty exception. Variable consideration is included in the transaction price only to the extent that it is probable that a significant turnover reversal will not occur when the uncertainty associated with the variable consideration is resolved. Payment terms for these types of contracts generally fall within 30 to 90 days of invoicing.

At December 31, 2018 and 2017, our reserves for sales deductions totaled $772.3 million and $942.8 million, respectively. These amounts relate primarily to our estimates of our unsettled obligations for returns and allowances, rebates and chargebacks. Our estimates are based on factors such as our direct and indirect customers' buying patterns and the estimated resulting contractual deduction rates, historical experience, specific known market events and estimated future trends, current contractual and statutory requirements, industry data, estimated customer stock levels, current contract sales terms with our direct and indirect customers and other competitive factors. Significant judgment and estimation is required in developing the foregoing and other relevant assumptions. The most significant sales deductions are further described below.

Returns and Allowances—Consistent with industry practice, we maintain a return policy that allows our customers to return products within a specified period of time both subsequent to and, in certain cases, prior to the products' expiration dates. Our return policy generally allows customers to receive credit for expired products within six months prior to expiration and within one year after expiration. Our provision for returns and allowances consists of our estimates for future product returns, pricing adjustments and delivery errors.

Rebates—Our provision for rebates, sales incentives and other allowances can generally be categorized into the following four types:

- direct rebates;
- indirect rebates;
- governmental rebates, including those for Medicaid, Medicare and TRICARE, among others; and
- managed-care rebates.

We establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives, DSA fees and other allowances. Some customers receive rebates upon attaining established sales volumes. Direct rebates are generally rebates paid to direct purchasing customers based on a percentage applied to a direct customer's purchases from us, including fees paid to wholesalers under our DSAs, as described above. Indirect rebates are rebates paid to indirect customers which have purchased our products from a wholesaler under a contract with us.

We are subject to rebates on sales made under governmental and managed-care pricing programs based on relevant statutes with respect to governmental pricing programs and contractual sales terms with respect to managed-care providers and group purchasing organizations. For example, we are required to provide a discount on our brand-name drugs to patients who fall within the Medicare Part D coverage gap, also referred to as the donut hole.

We participate in various federal and state government-managed programs whereby discounts and rebates are provided to participating government entities. For example, 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.

Chargebacks—We market and sell products to both: (i) direct customers including wholesalers, distributors, warehousing pharmacy chains and other direct purchasing groups and (ii) indirect customers including independent pharmacies, non-warehousing chains, managed-care organizations, group purchasing organizations and government entities. We enter into agreements with certain of our 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 credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price. Such credit is called a chargeback.

Contract Assets and Contract Liabilities. Contract assets represent the Group's right to consideration in exchange for goods or services that the Group has transferred to a customer when that right is conditioned on something other than the passage of time including, for example, the entity's future performance. The Group records turnover and a corresponding contract asset when it fulfills a contractual performance obligation, but must also fulfill one or more additional performance obligations before being entitled to payment. Once the Group's right to consideration becomes unconditional, the contract asset amount is reclassified as Debtors.

Contract liabilities represent the Group's obligation to transfer goods or services to a customer. The Group records a contract liability generally upon receipt of consideration in advance of fulfilling one or more of its contractual performance obligations. Upon completing each performance obligation, the corresponding contract liability amount is reversed and turnover is recognized.

Contract assets and liabilities related to rights and obligations arising from a single contract, or a series of contracts combined and accounted for as a single contract, are generally presented on a net basis. Contract assets and liabilities are further described in Note 11. Contract Assets and Liabilities.

Research and Development (R&D). Expenditures for research and development are expensed as incurred. Total R&D expenses include the costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, clinical trials, medical support of marketed products, upfront, milestone and other payments under third-party collaborations and contracts and other costs. R&D spending also includes enterprise-wide costs which support our overall R&D infrastructure. Tangible fixed assets that are acquired or constructed for research and development activities and that have alternate future uses are capitalized and depreciated over their estimated useful lives on a straight-line basis. Contractual upfront and milestone payments made to third parties are generally: (i) expensed as incurred up to the point of regulatory approval and (ii) capitalized and amortized over the related product's remaining useful life subsequent to regulatory approval. Amounts capitalized for such payments are included in Other intangibles, net in the Consolidated Balance Sheets.

Cash at Bank and In-hand. The Group considers all highly liquid money market instruments with an original maturity of three months or less when purchased to be cash at bank and in-hand. At December 31, 2018 and 2017, cash at bank and in-hand were deposited in financial institutions and consisted of immediately available fund balances and time deposits. The Group maintains its cash at bank and in-hand with financial institutions it believes to be well-known and stable.

Restricted Cash at Bank and In-hand. Cash at bank and in-hand that are restricted as to withdrawal or use under the terms of certain contractual agreements are excluded from Cash at bank and in-hand in the Consolidated Balance Sheets. For additional information see Note 6. Fair Value Measurements.

Marketable Securities. The Group has equity securities, which consist of investments in the stock of publicly traded companies. For additional information see Note 6. Fair Value Measurements.

Debtors. Debtor balances are stated at their net realizable value and the Group maintains an allowance for doubtful accounts against gross debtors. The allowance is not material to the Group's Consolidated Financial Statements at December 31, 2018 and 2017. In addition, debtors are reduced by certain sales deduction reserves where we have the right of offset with the customer.

Concentrations of Credit Risk. Financial instruments that potentially subject the Group to significant concentrations of credit risk consist primarily of cash at bank and on-hand, restricted cash at bank and on-hand, marketable debt securities and debtors. From time to time, we invest our excess cash at bank and in-hand in high-quality, liquid money market instruments and time deposits maintained by major banks and financial institutions. We have not experienced any losses on our cash at bank and in-hand.

We perform ongoing credit evaluations of our customers and generally do not require collateral. We have no history of significant losses from uncollectible accounts. Approximately 87% and 89% of our gross trade accounts receivable balances represent amounts due from three customers (Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation) at December 31, 2018 and 2017, respectively.

We do not expect our current or future exposures to credit risk to have a significant impact on our operations. However, there can be no assurance that any of these risks will not have an adverse effect on our business.

Stock. Stock consists of raw materials, work-in-process and finished goods. Stock that is in excess of the amount expected to be sold within one year is classified as long-term stock and is recorded in Other assets in the Consolidated Balance Sheets. The Group capitalizes stock costs associated with certain generic products prior to regulatory approval and product launch when it is reasonably certain, based on management's judgment of future commercial use and net realizable value, that the pre-launch stock will be saleable. The determination to capitalize is made on a product-by-product basis and generally occurs when: (i) the Group (or its third party development partners) has filed an ANDA that has been acknowledged by the FDA as containing sufficient information to allow the FDA to conduct its review in an efficient and timely manner and (ii) management is reasonably certain that all regulatory and legal requirements will be cleared. The Group could be required to write down previously capitalized costs related to pre-launch stock upon a change in such judgment, a denial or delay of approval by regulatory bodies, a delay in commercialization or other potential factors. Our stock is stated at the lower of cost or net realizable value. Cost is determined by the first-in, first-out method and includes materials, direct labor and an allocation of overhead. Net realizable value is determined by the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. When necessary, we write-down stock to net realizable value based on forecasted demand and market and regulatory conditions, which may differ from actual results.

Tangible fixed assets. Tangible fixed assets are generally stated at cost less accumulated depreciation. Major improvements are capitalized, while routine maintenance and repairs are expensed as incurred. Costs incurred during the construction or development of tangible fixed assets are capitalized as assets under construction. Once an asset has been put into service, depreciation expense is taken over the estimated useful life of the related assets or, in the case of leasehold improvements and capital lease assets, over the shorter of the estimated useful life or the lease term. Depreciation expense is recorded on a straight-line basis. Depreciation expense is not recorded on Assets held for sale. Gains and losses on disposals are included in Other income, net in the Consolidated Profit and Loss Account. Depreciation is based on the following estimated useful lives, as of December 31, 2018:

	Range of Useful Lives, from:
Buildings	10 years to 30 years
Machinery and equipment	2 years to 15 years
Leasehold improvements	Shorter of useful life or lease term
Computer equipment and software	1 year to 7 years
Assets under capital lease	Shorter of useful life or lease term
Furniture and fixtures	3 years to 10 years

Computer Software. The Group capitalizes certain costs incurred in connection with obtaining or developing internal-use software, including external direct costs of material and services, and payroll costs for employees directly involved with the software development. Capitalized software costs are included in Tangible fixed assets, net in the Consolidated Balance Sheets and depreciated beginning when the software project is substantially complete and the asset is ready for its intended use. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

Lease Accounting. The Group accounts for operating lease transactions by recording rent expense on a straight-line basis over the expected life of the lease, commencing on the date it gains possession of leased property. The Group includes tenant improvement allowances and rent holidays received from landlords and the effect of any rent escalation clauses as adjustments to straight-line rent expense over the expected life of the lease.

Capital lease transactions are reflected as a liability at the inception of the lease based on the present value of the minimum lease payments or, if lower, the fair value of the property. Assets under capital leases are recorded in Tangible fixed assets, net in the Consolidated Balance Sheets and depreciated in a manner similar to other Tangible fixed assets.

Certain construction projects may be accounted for as direct financing arrangements, whereby the Group records, over the construction period, the full cost of the asset in Tangible fixed assets, net in the Consolidated Balance Sheets. A corresponding liability is also recorded, net of leasehold improvements paid for by the Group, and is amortized over the expected lease term through monthly rental payments using an effective interest method. Assets recorded under direct financing arrangements are depreciated over the lease term.

Finite-Lived Intangible Assets. Our finite-lived intangible assets, which consist of license rights and developed technology, are initially recorded at fair value upon acquisition. There are several methods that can be used to determine fair value. For intangible assets, we typically use the income method. This method starts with our forecast of all of the expected future net cash flows. Turnover is estimated based on relevant market size and growth factors, expected industry trends, individual project life cycles and, if applicable, the life of any estimated period of marketing exclusivity, such as that granted by a patent. The pricing, margins and expense levels of similar products are considered if available. For certain licensed assets, our estimates of future cash flows consider periods covered by renewal options to the extent we have the intent and ability, at the date of the estimate, to renew the underlying license agreements. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the principal risks associated with the cash flow streams.

To the extent an intangible asset is deemed to have a finite life, it is then amortized over its estimated useful life using either the straight-line method or, in the case of certain developed technology assets, the economic benefit model. The values of these various assets are subject to continuing scientific, medical and marketplace uncertainty. Factors giving rise to our initial estimate of useful lives are subject to change. Significant changes to any of these factors may result in a reduction in the useful life of the asset and an acceleration of related amortization expense, which could cause our operating profit, net profit and net profit per share to decrease. Amortization expense is not recorded on assets held for sale.

Developed Technology. Our developed technology assets subject to amortization have useful lives ranging from 4 years to 20 years, with a weighted average useful life of approximately 11 years. We determine amortization periods and methods of amortization for developed technology assets based on our assessment of various factors impacting estimated useful lives and the timing and extent of estimated cash flows of the acquired assets, including the strength of the intellectual property protection of the product, contractual terms and various other competitive and regulatory issues.

License Rights. Our license rights subject to amortization have useful lives ranging from 10 years to 15 years, with a weighted average useful life of approximately 12 years. We determine amortization periods for licenses based on our assessment of various factors including the expected launch date of the product, the strength of the intellectual property protection of the product, contractual terms and various other competitive, developmental and regulatory issues.

Long-Lived Asset Impairment Testing. Long-lived assets, including tangible fixed assets and finite-lived intangible assets, are assessed for impairment whenever events or changes in circumstances indicate the carrying amounts of the assets may not be recoverable. Recoverability of an asset that will continue to be used in our operations is measured by comparing the carrying amount of the asset to the forecasted undiscounted future cash flows related to the asset. In the event the carrying amount of the asset exceeds its undiscounted future cash flows and the carrying amount is not considered recoverable, impairment may exist. An impairment loss, if any, is measured as the excess of the asset's carrying amount over its fair value, generally based on a discounted future cash flow method, independent appraisals or offers from prospective buyers. An impairment loss would be recognized in the Consolidated Profit and Loss Account in the period that the impairment occurs.

In-Process Research and Development Assets (IPR&D). IPR&D assets are considered indefinite-lived intangible assets. Similar to finite-lived intangible assets, IPR&D assets are initially recorded at fair value. While amortization expense is not initially recorded for IPR&D assets, these assets are subject to impairment reviews. Impairment tests for an IPR&D asset occur at least annually on October 1st of each year, but also whenever events or changes in circumstances indicate that the asset might be impaired. If the fair value of the intangible assets is less than its carrying amount, an impairment loss is recognized for the difference. For those assets that reach commercialization, the assets are reclassified and accounted for as finite-lived intangible assets.

Goodwill. Acquisitions meeting the definition of business combinations are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. While amortization expense is not recorded on goodwill, goodwill is subject to impairment reviews. Impairment tests for goodwill occur at least annually on October 1st of each year, but also whenever events or changes in circumstances indicate that the asset might be impaired.

Following our early adoption, effective January 1, 2017, of ASU 2017-04, we perform our goodwill impairment tests by comparing the fair value and carrying amount of each of our reporting units. Any goodwill impairment charge we recognize for a reporting unit is equal to the lesser of (i) the total goodwill allocated to that reporting unit and (ii) the amount by which that reporting unit's carrying amount exceeds its fair value.

Irish company law requires goodwill to be written off over a time period which does not exceed its useful life. Consistent with U.S. GAAP, the Group does not amortize goodwill over an arbitrary period as it is considered to have an indefinite life.

Contingencies. The Group is subject to various patent challenges, product liability claims, government investigations and other legal proceedings in the ordinary course of business. Legal fees and other expenses related to litigation are expensed as incurred and included in Selling, general and administrative expenses or Discontinued operations, net of tax in the Consolidated Profit and Loss Account. Contingent accruals and legal settlements are recorded in the Consolidated Profit and Loss Account as Litigation-related and other contingencies, net (or Discontinued operations, net in the case of vaginal mesh matters) when the Group determines that a loss is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our estimates of the probability and amount of any such liabilities involve significant judgment regarding future events. The Group records a receivable from its product liability insurance carriers only when the resolution of any dispute has been reached and realization of the potential claim for recovery is considered probable.

Contingent Consideration. Certain of the Group's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of operational and commercial milestones and/or royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the Group remeasures its contingent consideration liability to its current fair value, with changes recorded in earnings. Changes to any of the inputs used in determining fair value may result in fair value adjustments that differ significantly from the actual remeasurement adjustments recognized.

Share Repurchases. The Group accounts for the repurchase of ordinary shares, if any, at par value. Under applicable Irish law, ordinary shares repurchased are retired and not displayed separately as treasury stock. Upon retirement of the ordinary shares, the Group records the difference between the weighted average cost of such ordinary shares and the par value of the ordinary shares as an adjustment to Accumulated deficit in the Consolidated Balance Sheets.

Advertising Costs. Advertising costs are expensed as incurred and included in Selling, general and administrative expenses in the Consolidated Profit and Loss Account. Advertising costs amounted to $49.6 million and $42.0 million for the years ended December 31, 2018 and 2017, respectively.

Cost of Sales. Cost of sales includes all costs directly related to bringing both purchased and manufactured products to their final selling destination. Amounts include purchasing and receiving costs, direct and indirect costs to manufacture products including direct materials, direct labor and direct overhead expenses necessary to acquire and convert purchased materials and supplies into finished goods, royalties paid or owed by Endo on certain in-licensed products, inspection costs, depreciation of certain property, tangible fixed assets, amortization of intangible assets, warehousing costs, freight charges, costs to operate our equipment and other shipping and handling costs, among others.

Share-Based Compensation. The Group grants share-based compensation awards to certain employees and non-employee directors. Generally, the grant-date fair value of each award is recognized as expense over the requisite service period. However, expense recognition differs in the case of certain performance share units where the ultimate payout is performance-based. For these awards, at each reporting period, the Group estimates the ultimate payout and adjusts the cumulative expense based on its estimate and the percent of the requisite service period that has elapsed. Share-based compensation expense is reduced for estimated future forfeitures. These estimates are revised in future periods if actual forfeitures differ from the estimates. Changes in forfeiture estimates impact compensation expense in the period in which the change in estimate occurs. New ordinary shares are generally issued upon the exercise of stock options or vesting of stock awards by employees and non-employee directors. Refer to Note 16. Share-Based Compensation for additional discussion, including the accounting treatment for long-term cash incentive awards that will be settled in ordinary shares.

Foreign Currency. The Group operates in various jurisdictions both inside and outside of the U.S. While the Group's reporting currency is the U.S. dollar (USD), the Group has concluded that certain of its distinct and separable operations have functional currencies other than the USD. Further, certain of the Group's operations hold assets and liabilities and recognize profit and expenses denominated in various local currencies, which may differ from their functional currencies.

Assets and liabilities are first remeasured from local currency to functional currency, generally using end-of-period exchange rates. Foreign currency income and expenses are generally remeasured using average exchange rates in effect during the year. In the case of nonmonetary assets and liabilities such as stock, prepaid expenses, tangible fixed assets, goodwill and other intangible assets, and related profit and loss account amounts, such as depreciation expense, historical exchange rates are used for remeasurement. The net effect of remeasurement is included in Other income, net in the Consolidated Profit and Loss Account.

As part of the Group's consolidation process, assets and liabilities of entities with functional currencies other than the USD are translated into USD at end-of-period exchange rates. Income and expenses are translated using average exchange rates in effect during the year. The net effect of translation is included as foreign currency translation, a component of Other comprehensive (loss) income. Upon the sale or liquidation of an investment in a foreign operation, the Group records a reclassification adjustment out of Other comprehensive (loss) income for the corresponding amount of accumulated currency translation.

Income Taxes. The Group accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. The Group records net deferred tax assets to the extent it believes these assets will more likely than not be realized. In making such a determination, the Group considers all available positive and negative evidence, including projected future taxable income, tax-planning strategies and results of recent operations. In the event that the Group were to determine that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, the Group would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income tax.

The Group records uncertain tax positions on the basis of a two-step process whereby the Group first determines whether it is more likely than not that the tax positions will be sustained based on the technical merits of the position and then measures those tax positions that meet the more-likely-than-not recognition threshold. The Group recognizes the largest amount of tax benefit that is greater than 50% likely to be realized upon ultimate settlement with the tax authority. The Group recognizes interest and penalties related to unrecognized tax benefits within the Income tax expense (benefit) line in the Consolidated Profit and Loss Account. Accrued interest and penalties are included within the related tax liability line in the Consolidated Balance Sheets.

Comprehensive Income. Comprehensive income or loss includes all changes in equity during a period except those that resulted from investments by or distributions to a company's shareholders. Other comprehensive income or loss refers to turnover, expenses, gains and losses that are included in comprehensive income, but excluded from net profit as these amounts are recorded directly as an adjustment to shareholders' equity.

Recent Accounting Pronouncements

Recently Issued Accounting Pronouncements Not Yet Adopted at December 31, 2018

In February 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-02, *"Leases (Topic 842)"* (ASU 2016-02) to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under the new guidance, lessees are required to recognize a lease liability, which represents the discounted obligation to make future minimum lease payments, and a corresponding right-of-use asset on the balance sheet for most leases. In July 2018, the FASB issued ASU No. 2018-10, *"Codification Improvements to Topic 842, Leases"* (ASU 2018-10), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU No. 2018-11, *"Leases (Topic 842) - Targeted Improvements"* (ASU 2018-11), which addresses implementation issues related to the new lease standard. This guidance is effective for the Group as of January 1, 2019 and the Group will adopt this guidance using the modified retrospective approach and will recognize a cumulative-effect adjustment to the opening balance of Accumulated deficit in that period. This guidance includes a number of optional practical expedients that the Group may elect to apply, including an expedient that permits lease agreements that are twelve months or less to be excluded from the balance sheet. The Group is finalizing the impact that this new guidance will have on its consolidated financial statements, including its disclosures. The primary impact upon adoption will be the recognition, on a discounted basis, of the Group's minimum commitments under noncancelable operating leases as right of use assets and obligations on the consolidated balance sheets. This will result in a significant increase in assets and liabilities on the Group's consolidated balance sheets. In preparation for the adoption of this guidance, the Group's process of identifying and validating the Group's lease information and evaluating the impact that this new guidance will have on its processes and controls is substantially complete.

In August 2018, the FASB issued ASU No. 2018-13, "*Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*" (ASU 2018-13). ASU 2018-13 modifies the disclosure requirements on fair value measurements in *Accounting Standards Codification Topic 820, Fair Value Measurement*. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Certain aspects of ASU 2018-13 require prospective treatment, while others require retrospective treatment. Early adoption is permitted. The Group is currently evaluating the impact of ASU 2018-13 on the Group's disclosures.

In August 2018, the FASB issued ASU No. 2018-15, "*Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*" (ASU 2018-15). ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (including hosting arrangements where a software license is deemed to exist). ASU 2018-15 also requires the customer to expense any such capitalized implementation costs over the term of the hosting arrangement and to apply the existing impairment guidance for long-lived assets to such capitalized costs. Additionally, ASU 2018-15 sets forth required disclosures and guidance on financial statement classification for expenses, cash flows and balances related to implementation costs within the scope of ASU 2018-15. ASU 2018-15 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years; however, early adoption is permitted. The guidance may be applied retrospectively or prospectively to implementation costs incurred after the date of adoption. The Group will adopt this guidance during the first quarter of 2019 on a prospective basis.

In November 2018, the FASB issued ASU No. 2018-18, "*Clarifying the Interaction Between Topic 808 and Topic 606"* (ASU 2018-18). The main provisions of ASU 2018-18 include: (i) clarifying that certain transactions between collaborative arrangement participants should be accounted for as turnover when the collaborative arrangement participant is a customer in the context of a unit of account and (ii) precluding the presentation of transactions with collaborative arrangement participants that are not directly related to sales to third parties together with turnover. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606 (January 1, 2018 for the Group) and early adoption is permitted. The Group is currently evaluating the impact of ASU 2018-18 on the Group's consolidated results of operations, financial position and disclosures.

Recent Accounting Pronouncements Adopted or Otherwise Effective as of December 31, 2018

In May 2014, the FASB issued ASU No. 2014-09, *"Revenue from Contracts with Customers"* (ASU 2014-09), which was subsequently amended and supplemented by several additional ASUs including:

- ASU No. 2015-14, "*Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date,"* (issued in August 2015), which deferred the effective date of ASU 2014-09 by one year, such that ASU 2014-09 became effective for Endo for annual and interim reporting periods beginning after December 15, 2017;
- ASU No. 2016-08, *"Revenue from Contracts with Customers (Topic 606): Principal versus Agent Consideration (Reporting Revenue Gross versus Net)"* (issued in March 2016), which clarified the guidance on reporting turnover as a principal versus agent;
- ASU No. 2016-10, *"Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing"* (issued in April 2016), which clarified the guidance on identifying performance obligations and accounting for intellectual property licenses; and
- ASU No. 2016-12, *"Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients"* and ASU No. 2016-20, *"Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers,"* (issued in May 2016 and December 2016, respectively), which amended certain narrow aspects of Topic 606.

These ASUs have generally been codified in *Accounting Standards Codification Topic 606,* "*Revenue from Contracts with Customers*", and are collectively referred to herein as ASC 606. ASC 606 supersedes the turnover recognition requirements in *Accounting Standards Codification Topic 605, "Revenue Recognition"* (ASC 605), and requires entities to recognize turnover when control of promised goods or services is transferred to customers at an amount that reflects the consideration to which entities expect to be entitled in exchange for those goods or services.

The Group adopted ASC 606 on January 1, 2018 using the modified retrospective method for all turnover-generating contracts, including modifications thereto, that were not completed contracts at the date of adoption. Under the modified retrospective method, results beginning on January 1, 2018 are presented under ASC 606, while the comparative prior period results continue to be presented under ASC 605 based on the accounting standards originally in effect for such periods. As a result of adopting ASC 606, the Group recorded a net decrease of $3.1 million to its accumulated deficit at January 1, 2018, representing the cumulative impact of adopting ASC 606.

The current year impact of adoption on our Consolidated Profit and Loss Account and Consolidated Balance Sheets is as follows (in thousands, except per share amounts):

	Year Ended December 31, 2018		
Profit and Loss Account:	**Amounts reported under ASC 606**	**Amounts assuming continued application of ASC 605**	**Effect of adoption of ASC 606 (1)**
Total turnover	$ 2,947,078	$ 2,947,930	$ (852)
Cost of sales	$ 1,631,682	$ 1,633,294	$ (1,612)
Other income, net	$ (51,953)	$ (50,953)	$ (1,000)
Loss from continuing operations	$ (961,767)	$ (963,527)	$ 1,760
Net loss	$ (1,031,469)	$ (1,033,229)	$ 1,760
Net loss per share—Basic:			
Continuing operations	$ (4.29)	$ (4.30)	$ 0.01
Total basic	$ (4.61)	$ (4.61)	$ —
Net loss per share—Diluted:			
Continuing operations	$ (4.29)	$ (4.30)	$ 0.01
Total diluted	$ (4.61)	$ (4.61)	$ —

(1) Amounts may not add due to rounding.

	At December 31, 2018		
Balance Sheet:	**Amounts reported under ASC 606**	**Amounts assuming continued application of ASC 605**	**Effect of adoption of ASC 606**
Assets:			
Stock, net	$ 322,179	$ 329,684	$ (7,505)
Prepaid expenses and other current assets	$ 56,139	$ 46,832	$ 9,307
Other assets	$ 66,993	$ 64,235	$ 2,758
Liabilities:			
Accounts payable and accrued expenses	$ 1,009,200	$ 1,009,476	$ (276)
Shareholders' (deficit) equity:			
Accumulated deficit	$ (9,124,932)	$ (9,129,768)	$ 4,836

In May 2017, the FASB issued ASU No. 2017-09, *"Compensation - Stock Compensation"* (ASU 2017-09). ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. It is intended to reduce both (1) diversity in practice and (2) cost and complexity when accounting for changes to the terms or conditions of share-based payment awards. ASU 2017-09 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. The Group adopted the new standard on January 1, 2018, effective for any award modified on or after the adoption date.

NOTE 3. DISCONTINUED OPERATIONS AND DIVESTITURES

Astora

The operating results of the Group's Astora business, which the Board of Directors resolved to wind-down in 2016, are reported as Discontinued operations, net of tax in the Consolidated Profit and Loss Account for all periods presented.

The following table provides the operating results of Astora Discontinued operations, net of tax, for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Turnover	$ —	$ 338
Litigation-related and other contingencies, net	$ 34,000	$ 775,474
Asset impairment charges	$ —	$ —
Loss from discontinued operations before income taxes	$ (69,702)	$ (816,426)
Income tax benefit	$ —	$ (13,704)
Discontinued operations, net of tax	$ (69,702)	$ (802,722)

Substantially all of the amounts reported in the table above as Litigation-related and other contingencies, net relate to charges for vaginal-mesh-related matters, which are further described in Note 13. Commitments and Contingencies. Loss from discontinued operations before income taxes also includes mesh-related legal defense costs, restructuring-related costs and certain other items.

The cash flows from discontinued operating activities related to Astora included the impact of net losses of $69.7 million and $802.7 million for the years ended December 31, 2018 and 2017, respectively, and the impact of cash activity related to vaginal mesh cases. There were no material net cash flows related to Astora discontinued investing activities during the years ended December 31, 2018 and 2017. There was no depreciation or amortization during the years ended December 31, 2018 or 201 related to Astora.

Litha

During the fourth quarter of 2016, the Group initiated a process to sell Litha and, on February 27, 2017, the Group entered into a definitive agreement to sell Litha to Acino Pharma AG (Acino). The sale closed on July 3, 2017 and the Group received net cash proceeds of approximately $94.2 million, after giving effect to cash and net working capital purchase price adjustments, as well as a short-term receivable of $4.4 million, which was subsequently collected in October 2017. No additional gain or loss was recognized upon sale. However, in December 2017, Acino became obligated to pay $10.1 million of additional consideration to the Group related to the settlement of certain contingencies set forth in the purchase agreement, which was subsequently paid to the Group in January 2018. In December 2017, the Group recorded a short-term receivable and a gain on the sale of Litha for this amount. The gain was recorded in Other income, net in the Consolidated Profit and Loss Account. Litha was part of the Group's International Pharmaceuticals segment. Litha does not meet the requirements for treatment as a discontinued operation.

Somar

On June 30, 2017, the Group entered into a definitive agreement to sell Somar and all of the securities thereof, to AI Global Investments (Netherlands) PCC Limited acting for and on behalf of the Soar Cell (the Purchaser). The sale closed on October 25, 2017 and the Purchaser paid an aggregate purchase price of approximately $124 million in cash, after giving effect to estimated cash, debt and net working capital purchase price adjustments. The Group recognized a $1.3 million loss upon sale. Somar was part of the Group's International Pharmaceuticals segment. Somar does not meet the requirements for treatment as a discontinued operation.

Continuing Operations and Discontinued Operations

The Group is presenting a bridge of the continuing operations financial statements presented with the financial statements of the group. Treatment of discontinued operations presented are in accordance with U.S. GAAP.

The following profit and loss accounts show reconciliations of continuing operations and discontinued operations to the global company for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31, 2018		
	Continuing Operations	Discontinued Operations	Global Company
TURNOVER	$ 2,947,078	$ —	$ 2,947,078
Cost of sales	1,631,682	—	1,631,682
GROSS PROFIT	$ 1,315,396	$ —	$ 1,315,396
Selling, general and administrative expenses	646,037	32,894	678,931
Research and development expenses	185,826	—	185,826
Litigation-related and other contingency expenses	13,809	34,000	47,809
Asset impairment charges	916,939	—	916,939
Acquisition-related and integration items	21,914	—	21,914
OPERATING LOSS	$ (469,129)	$ (66,894)	$ (536,023)
INTEREST RECEIVABLE AND SIMILAR INCOME	(13,194)	—	(13,194)
INTEREST PAYABLE AND SIMILAR CHARGES	534,850	—	534,850
OTHER INCOME, NET	(51,953)	2,808	(49,145)
LOSS FROM CONTINUING OPERATIONS BEFORE TAXATION	$ (938,832)	$ (69,702)	$ (1,008,534)
TAX BENEFIT FROM COINTINUING OPERATIONS	22,935	—	22,935
LOSS FROM CONTINUING OPERATIONS	$ (961,767)	$ (69,702)	$ (1,031,469)
DISCONTINUED OPERATIONS, NET OF TAX	(69,702)	69,702	—
LOSS FOR THE FINANCIAL YEAR	$ (1,031,469)	$ —	$ (1,031,469)

	Year Ended December 31, 2017		
	Continuing Operations	Discontinued Operations	Global Company
TURNOVER	$ 3,468,858	$ 338	$ 3,469,196
Cost of sales	2,228,530	—	2,228,530
GROSS PROFIT	$ 1,240,328	$ 338	$ 1,240,666
Selling, general and administrative expenses	629,874	42,870	672,744
Research and development expenses	172,067	—	172,067
Litigation-related and other contingency expenses	185,990	775,474	961,464
Asset impairment charges	1,154,376	—	1,154,376
Acquisition-related and integration items	58,086	—	58,086
OPERATING LOSS	$ (960,065)	$ (818,006)	$ (1,778,071)
INTEREST RECEIVABLE AND SIMILAR INCOME	(6,466)	—	(6,466)
INTEREST PAYABLE AND SIMILAR CHARGES	494,694	—	494,694
LOSS ON EXTINGUISHMENT OF DEBT	51,734	—	51,734
OTHER INCOME, NET	(17,023)	(1,580)	(18,603)
LOSS FROM CONTINUING OPERATIONS BEFORE TAXATION	$ (1,483,004)	$ (816,426)	$ (2,299,430)
TAX BENEFIT FROM COINTINUING OPERATIONS	(250,293)	(13,704)	(263,997)
LOSS FROM CONTINUING OPERATIONS	$ (1,232,711)	$ (802,722)	$ (2,035,433)
DISCONTINUED OPERATIONS, NET OF TAX	(802,722)	802,722	—
LOSS FOR THE FINANCIAL YEAR	$ (2,035,433)	$ —	$ (2,035,433)

The Group did not have held for sale assets and liabilities as of December 31, 2018 or 2017.

NOTE 4. RESTRUCTURING

Set forth below are disclosures relating to restructuring initiatives that resulted in material expenses or cash expenditures during any of the years ended December 31, 2018 or 2017 or had material restructuring liabilities at either December 31, 2018 or December 31, 2017. Employee separation, retention and certain other employee benefit-related costs related to our restructurings are expensed ratably over the requisite service period. Other restructuring costs are generally expensed as incurred.

2016 U.S. Generic Pharmaceuticals Restructuring Initiative

As part of the ongoing U.S. Generic Pharmaceuticals integration efforts initiated in connection with the acquisition of Par in September 2015, the Group announced a restructuring initiative in May 2016 to optimize its product portfolio and rationalize its manufacturing sites to expand product margins (the 2016 U.S. Generic Pharmaceuticals Restructuring Initiative). These measures included certain cost savings initiatives, including a reduction in headcount and the disposal of our Charlotte, North Carolina manufacturing facility (the Charlotte facility). On October 31, 2016, we entered into a definitive agreement to sell the Charlotte facility for cash proceeds of $14 million. The transaction closed in January 2017.

As a result of the 2016 U.S. Generic Pharmaceuticals Restructuring Initiative, the Group incurred pre-tax charges of $1.0 million during the year ended December 31, 2017. The Group did not incur any pre-tax restructuring expenses related to this initiative during the year ended December 31, 2018. The 2017 charges related primarily to employee separation and other benefit-related costs.

These charges are included in the U.S. Generic Pharmaceuticals segment and are included in Asset impairment charges, Cost of sales and Selling, general and administrative expenses in the Consolidated Profit and Loss Account. The Group does not expect to incur additional significant expenses related to this restructuring initiative.

Substantially all related cash payments were made by the end of 2017.

2016 U.S. Branded - Specialty & Established Pharmaceuticals Restructuring Initiative

In December 2016, the Group announced that it was terminating its worldwide license and development agreement with BioDelivery Sciences International, Inc. (BDSI) for BELBUCA™ and returning the product to BDSI. This termination was completed on January 6, 2017. As a result of this announcement and a comprehensive assessment of its product portfolio, the Group restructured its U.S. Branded - Specialty & Established Pharmaceuticals segment sales organization during the fourth quarter of 2016 (the 2016 U.S. Branded - Specialty & Established Pharmaceuticals Restructuring Initiative), which included the elimination of an approximate 375-member U.S. Branded - Specialty & Established Pharmaceuticals pain field sales force and the termination of certain contracts.

The Group did not incur any material pre-tax charges as a result of the 2016 U.S. Branded - Specialty & Established Pharmaceuticals Restructuring Initiative during the years ended December 31, 2018 or 2017, and does not expect to incur additional material pre-tax restructuring-related expenses related to this initiative. Actions related to this initiative were completed by December 31, 2016 and substantially all of the cash payments were made by the end of 2017.

The liability related to the 2016 U.S. Branded - Specialty & Established Pharmaceuticals Restructuring Initiative is included in Accounts payable and accrued expenses in the Consolidated Balance Sheets. Changes to this liability during the year ended December 31, 2017 were as follows (in thousands):

	Employee Separation and Other Benefit-Related Costs	Contract Termination Charges	Total
Liability balance as of January 1, 2017	$ 16,544	$ 5,224	$ 21,768
Cash distributions	(16,544)	(5,224)	(21,768)
Liability balance as of December 31, 2017	$ —	$ —	$ —

January 2017 Restructuring Initiative

On January 26, 2017, the Group announced a restructuring initiative implemented as part of its ongoing organizational review (the January 2017 Restructuring Initiative). This restructuring was intended to further integrate, streamline and optimize the Group's operations by aligning certain corporate and research and development (R&D) functions with its recently restructured U.S. generics and U.S. branded business units in order to create efficiencies and cost savings. As part of this restructuring, the Group undertook certain cost reduction initiatives, including a reduction of approximately 90 positions of its workforce, primarily related to corporate and branded R&D functions in Malvern, Pennsylvania and Chestnut Ridge, New York, a streamlining of general and administrative expenses, an optimization of commercial spend and a refocusing of research and development efforts.

During the year ended December 31, 2017, the Group incurred total pre-tax charges of approximately $15.1 million related to employee separation and other benefit-related costs. Of the total charges incurred, $6.9 million was included in the U.S. Branded - Specialty & Established Pharmaceuticals segment, $4.9 million was included in Corporate unallocated costs and $3.3 million was included in the U.S. Generic Pharmaceuticals segment. These charges were included in Selling, general and administrative expenses in the Consolidated Profit and Loss Account.

The Group did not incur any other material pre-tax charges as a result of the January 2017 Restructuring Initiative and does not expect to incur additional material pre-tax restructuring-related expenses related to this initiative. Substantially all of the actions associated with this restructuring were completed by the end of April 2017.

The liability related to the January 2017 Restructuring Initiative is included in Accounts payable and accrued expenses in the Consolidated Balance Sheets. Changes to this liability during the years ended December 31, 2018 and 2017 were as follows (in thousands):

	Total
Liability balance as of January 1, 2017	$ —
Expenses	15,072
Cash distributions	(12,391)
Liability balance as of December 31, 2017	$ 2,681
Cash distributions	(2,681)
Liability balance as of December 31, 2018	$ —

2017 U.S. Generic Pharmaceuticals Restructuring Initiative

On July 21, 2017, the Group announced that after completing a comprehensive review of its manufacturing network, it would be ceasing operations and closing its manufacturing and distribution facilities in Huntsville, Alabama (the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative). The closure of the facilities was completed in June 2018 and the facilities were sold in the fourth quarter of 2018 for net cash proceeds of $23.1 million, resulting in a net gain on disposal of $12.5 million, which is included in Other income, net in the Consolidated Profit and Loss Account.

As a result of the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative, the Group incurred pre-tax charges of $61.6 million and $286.7 million during the years ended December 31, 2018 and 2017, respectively. The 2018 amount does not include the $12.5 million gain on the sale of the Huntsville facilities described above.

During the year ended December 31, 2018, the expenses consisted of charges relating to accelerated depreciation of $35.2 million, employee separation, retention and other benefit-related costs of $9.1 million, asset impairment charges of $2.6 million and certain other charges of $14.7 million, partially offset by the gain on the sale of the Huntsville facilities described above.

During the year ended December 31, 2017, the expenses included accelerated depreciation charges of $123.3 million, employee separation, retention and other benefit-related costs of $29.6 million, certain intangible asset and tangible fixed assets impairment charges of $104.7 million, charges to increase excess stock reserves of $12.1 million and certain other charges of $17.0 million.

These charges are included in the U.S. Generic Pharmaceuticals segment. Accelerated depreciation, employee separation, retention and other benefit-related costs and charges to increase excess stock reserves are included in Cost of sales in the Consolidated Profit and Loss Account. Impairment charges are included in Asset impairment charges. Certain other charges are included in both Cost of sales and Selling, general and administrative expenses.

The Group did not incur any other material pre-tax charges as a result of the January 2017 Restructuring Initiative and does not expect to incur additional material pre-tax restructuring-related expenses related to this initiative.

The liability related to the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative is primarily included in Accounts payable and accrued expenses in the Consolidated Balance Sheets. Changes to this liability during the years ended December 31, 2018 and 2017 were as follows (in thousands):

	Employee Separation and Other Benefit-Related Costs	Other Restructuring Costs	Total
Liability balance as of January 1, 2017	$ —	$ —	$ —
Expenses	29,553	13,724	43,277
Cash distributions	(6,578)	(12,114)	(18,692)
Liability balance as of December 31, 2017	$ 22,975	$ 1,610	$ 24,585
Expenses	9,090	11,294	20,384
Cash distributions	(27,826)	(12,856)	(40,682)
Liability balance as of December 31, 2018	$ 4,239	$ 48	$ 4,287

Substantially all cash payments are expected to be made by the end of the third quarter in 2019.

January 2018 Restructuring Initiative

In January 2018, the Group initiated a restructuring initiative that included a reorganization of its U.S. Generic Pharmaceuticals segment's research and development network, a further simplification of the Group's manufacturing networks and a group-wide unification of certain corporate functions (the January 2018 Restructuring Initiative).

As a result of the January 2018 Restructuring Initiative, the Group incurred pre-tax charges of $23.5 million and $2.6 million during the years ended December 31, 2018 and 2017, respectively.

The expenses in 2018 consisted primarily of employee separation, retention and other benefit-related costs of $21.7 million and certain other charges of $1.8 million. Of the total charges incurred, $10.6 million are included in the U.S. Generic Pharmaceuticals segment, $5.2 million are included in Corporate unallocated costs, $3.9 million are included in the U.S. Branded - Sterile Injectables segment, $3.1 million are included in the International Pharmaceuticals segment and $0.7 million are included in the U.S. Branded - Specialty & Established Pharmaceuticals segment.

The expenses in 2017 consisted of certain tangible fixed asset impairment charges of $2.0 million and certain other charges of $0.6 million. These charges are primarily included in the U.S. Generic Pharmaceuticals segment.

Employee separation, retention and other benefit-related costs are included in Cost of sales, Selling, general and administrative and Research and development expenses in the Consolidated Profit and Loss Account. Certain other charges are primarily included in Selling, general and administrative expenses. Impairment charges are included in Asset impairment charges.

The Group did not incur any other material pre-tax charges as a result of the January 2018 Restructuring Initiative and does not expect to incur additional material pre-tax restructuring-related expenses related to this initiative.

The liability related to the January 2018 Restructuring Initiative is primarily included in Accounts payable and accrued expenses in the Consolidated Balance Sheets. Changes to this liability during the year ended December 31, 2018 were as follows (in thousands):

	Employee Separation and Other Benefit-Related Costs	Other Restructuring Costs	Total
Liability balance as of January 1, 2018	$ —	$ 650	$ 650
Expenses	21,754	1,764	23,518
Cash distributions	(20,925)	(2,094)	(23,019)
Liability balance as of December 31, 2018	$ 829	$ 320	$ 1,149

Substantially all cash payments are expected to be made by the end of the second quarter in 2019.

NOTE 5. SEGMENT RESULTS

As of January 1, 2018, we made changes to our reportable segments. Following these changes, the four reportable business segments in which we operate are: (1) U.S. Branded - Specialty & Established Pharmaceuticals, (2) U.S. Branded - Sterile Injectables, (3) U.S. Generic Pharmaceuticals and (4) International Pharmaceuticals. Previously, we had three reportable segments: (1) U.S. Generic Pharmaceuticals, (2) U.S. Branded Pharmaceuticals and (3) International Pharmaceuticals. The updates to our reportable segments were made based on first quarter 2018 changes to the way we manage and evaluate our business.

Our new U.S. Branded - Sterile Injectables segment consists of our sterile injectables product portfolio, which was previously part of our former U.S. Generic Pharmaceuticals segment. Our new U.S. Generic Pharmaceuticals segment represents the remainder of our former U.S. Generic Pharmaceuticals segment. Additionally, our former U.S. Branded Pharmaceuticals segment has been renamed "U.S. Branded - Specialty & Established Pharmaceuticals."

Our segments reflect the level at which the chief operating decision maker regularly reviews financial information to assess performance and to make decisions about resources to be allocated. Each segment derives turnover from the sales or licensing of its respective products and is discussed in more detail below.

We evaluate segment performance based on each segment's adjusted profit from continuing operations before income tax, which we define as Loss from continuing operations before income tax and before certain upfront and milestone payments to partners; acquisition-related and integration items, including transaction costs and changes in the fair value of contingent consideration; cost reduction and integration-related initiatives such as separation benefits, retention payments, other exit costs and certain costs associated with integrating an acquired company's operations; asset impairment charges; amortization of intangible assets; stock step-up recorded as part of our acquisitions; litigation-related and other contingent matters; gains or losses from early termination of debt; gains or losses from the sales of businesses and other assets; foreign currency gains or losses on intercompany financing arrangements; and certain other items.

Certain of the corporate expenses incurred by the Group are not attributable to any specific segment. Accordingly, these costs are not allocated to any of the Group's segments and are included in the results below as "Corporate unallocated costs." Interest income and expense are also considered corporate items and not allocated to any of the Group's segments. The Group's consolidated adjusted profit from continuing operations before income tax is equal to the combined results of each of its segments less these unallocated corporate items.

U.S. Branded - Specialty & Established Pharmaceuticals

Our U.S. Branded - Specialty & Established Pharmaceuticals segment includes a variety of branded prescription products to treat and manage conditions in urology, urologic oncology, endocrinology, pain and orthopedics. The products in this segment include XIAFLEX®, SUPPRELIN® LA, NASCOBAL® Nasal Spray, TESTOPEL®, AVEED®, PERCOCET®, VOLTAREN® Gel, LIDODERM®, FORTESTA® Gel, EDEX® and TESTIM®, among others.

U.S. Branded - Sterile Injectables

Our U.S. Branded - Sterile Injectables segment consists primarily of branded sterile injectable products such as VASOSTRICT®, ADRENALIN® and APLISOL®, among others, and certain generic sterile injectable products, including ertapenem for injection and ephedrine sulfate injection, among others.

U.S. Generic Pharmaceuticals

Our U.S. Generic Pharmaceuticals segment consists of a differentiated product portfolio including solid oral extended-release, solid oral immediate-release, liquids, semi-solids, patches, powders, ophthalmics and sprays and includes products in the pain management, urology, central nervous system disorders, immunosuppression, oncology, women's health and cardiovascular disease markets, among others.

International Pharmaceuticals

Our International Pharmaceuticals segment includes a variety of specialty pharmaceutical products sold outside the U.S., primarily in Canada through our operating company Paladin. This segment's key products serve growing therapeutic areas, including attention deficit hyperactivity disorder, pain, women's health and oncology. This segment also included: (i) our South African Litha business, which was sold in July 2017, and (ii) our Latin American Somar business, which was sold in October 2017.

The following represents selected information for the Group's reportable segments for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Net turnover from external customers:		
U.S. Branded - Specialty & Established Pharmaceuticals	$ 862,832	$ 957,525
U.S. Branded - Sterile Injectables	929,566	750,471
U.S. Generic Pharmaceuticals	1,012,215	1,530,530
International Pharmaceuticals (1)	142,465	230,332
Total net turnover from external customers	$ 2,947,078	$ 3,468,858
Adjusted profit from continuing operations before income tax:		
U.S. Branded - Specialty & Established Pharmaceuticals	$ 368,790	$ 485,515
U.S. Branded - Sterile Injectables	695,363	563,103
U.S. Generic Pharmaceuticals	317,892	501,249
International Pharmaceuticals	59,094	58,308
Total segment adjusted profit from continuing operations before income tax	$ 1,441,139	$ 1,608,175

(1) Turnover generated by our International Pharmaceuticals segment is primarily attributable to external customers located in Canada and, prior to the sale of Litha in July 2017 and Somar in October 2017, South Africa and Latin America.

There was no material turnover from external customers attributed to an individual country outside of the U.S. during any of the periods presented. There were no material tangible long-lived assets in an individual country other than the U.S. as of December 31, 2018 or December 31, 2017.

The table below provides reconciliations of our Total consolidated loss from continuing operations before income tax, which is determined in accordance with U.S. generally accepted accounting principles (U.S. GAAP), to our total segment adjusted profit from continuing operations before income tax for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Total consolidated loss from continuing operations before income tax	$ (938,832)	$ (1,483,004)
Interest expense, net	521,656	488,228
Corporate unallocated costs (1)	200,592	165,298
Amortization of intangible assets	622,339	773,766
Stock step-up and certain manufacturing costs that will be eliminated pursuant to integration plans	261	390
Upfront and milestone payments to partners	45,108	9,483
Separation benefits and other cost reduction initiatives (2)	86,295	212,448
Certain litigation-related and other contingencies, net (3)	13,809	185,990
Asset impairment charges (4)	916,939	1,154,376
Acquisition-related and integration items (5)	21,914	58,086
Loss on extinguishment of debt	—	51,734
Foreign currency impact related to the remeasurement of intercompany debt instruments	(5,486)	(1,403)
Other, net (6)	(43,456)	(7,217)
Total segment adjusted profit from continuing operations before income tax	$ 1,441,139	$ 1,608,175

(1) Amounts include certain corporate overhead costs, such as headcount, facility and corporate litigation expenses and certain other income and expenses.

(2) Amounts in 2018 primarily relate to employee separation costs of $31.7 million, accelerated depreciation of $35.2 million, charges to increase excess stock reserves of $2.9 million and other charges of $16.5 million, each of which related primarily to our restructuring initiatives. Amounts in 2017 primarily relate to employee separation costs of $53.0 million, accelerated depreciation of $123.7 million, charges to increase excess stock reserves of $13.7 million and other charges of $22.0 million. These charges were related primarily to the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative. See Note 4. Restructuring for discussion of our material restructuring initiatives.

(3) Amounts include adjustments for Litigation-related and other contingencies, net as further described in Note 13. Commitments and Contingencies.

(4) Amounts primarily relate to charges to impair goodwill and intangible assets as further described in Note 9. Goodwill and Other Intangibles as well as charges to write down certain tangible fixed assets as further described in Note 4. Restructuring, Note 6. Fair Value Measurements and Note 8. Tangible Fixed Assets.

(5) Amounts include charges due to changes in the fair value of contingent consideration of $19.9 million and $49.9 million, respectively. All other amounts are directly related to costs associated with acquisition and integration efforts.
(6) Amounts in 2018 primarily relate to gains on sales of businesses and other assets, as further described in Note 19. Other Income, Net.

The Group disaggregates its turnover from contracts with customers into the categories included in the table below (in thousands). The Group believes these categories depict how the nature, timing and uncertainty of turnover and cash flows are affected by economic factors.

	2018	2017
U.S. Branded - Specialty & Established Pharmaceuticals:		
Specialty Products:		
XIAFLEX®	$ 264,638	$ 213,378
SUPPRELIN® LA	81,707	86,211
Other Specialty (1)	156,607	153,384
Total Specialty Products	$ 502,952	$ 452,973
Established Products:		
PERCOCET®	$ 122,901	$ 125,231
VOLTAREN® Gel	57,700	68,780
OPANA® ER	—	83,826
Other Established (2)	179,279	226,715
Total Established Products	$ 359,880	$ 504,552
Total U.S. Branded - Specialty & Established Pharmaceuticals (3)	$ 862,832	$ 957,525
U.S. Branded - Sterile Injectables:		
VASOSTRICT®	$ 453,767	$ 399,909
ADRENALIN®	143,489	76,523
Ertapenem for injection	57,668	—
Other Sterile Injectables (4)	274,642	274,039
Total U.S. Branded - Sterile Injectables (3)	$ 929,566	$ 750,471
Total U.S. Generic Pharmaceuticals (5)	$ 1,012,215	$ 1,530,530
Total International Pharmaceuticals (6)	$ 142,465	$ 230,332
Total Turnover	$ 2,947,078	$ 3,468,858

(1) Products included within Other Specialty include NASCOBAL® Nasal Spray, TESTOPEL® and AVEED®.
(2) Products included within Other Established include, but are not limited to, LIDODERM®, FORTESTA® Gel, EDEX® and TESTIM® including the authorized generics of TESTIM® and FORTESTA® Gel.
(3) Individual products presented above represent the top two performing products in each product category and/or any product having turnover in excess of $100 million during any of the years ended December 31, 2018 and 2017 or $25 million during any quarterly period in 2018.
(4) Products included within Other Sterile Injectables include, but are not limited to, APLISOL® and ephedrine sulfate injection.
(5) The U.S. Generic Pharmaceuticals segment is comprised of a portfolio of products that are generic versions of branded products, are distributed primarily through the same wholesalers, generally have no intellectual property protection and are sold within the U.S. Combined sales of ezetimibe tablets and quetiapine ER tablets, for which we lost temporary marketing exclusivity during the second quarter of 2017, made up 7% of consolidated total turnover in 2017. No other individual product within this segment has exceeded 5% of consolidated total turnover for the periods presented.
(6) The International Pharmaceuticals segment, which accounted for 5% and 7% of consolidated total turnover in 2018 and 2017, respectively, includes a variety of specialty pharmaceutical products sold outside the U.S., primarily in Canada through our operating company Paladin. This segment also included Litha, which was sold in July 2017, and Somar, which was sold in October 2017.

The following represents depreciation expense for our reportable segments for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
U.S. Branded - Specialty & Established Pharmaceuticals	$ 14,542	$ 16,957
U.S. Branded - Sterile Injectables	10,500	8,411
U.S. Generic Pharmaceuticals	66,016	174,652
International Pharmaceuticals	4,925	3,332
Corporate unallocated	5,385	6,647
Total depreciation expense	$ 101,368	$ 209,999

Asset information is not reviewed or included within our internal management reporting. Therefore, the Group has not disclosed asset information for each reportable segment.

NOTE 6. FAIR VALUE MEASUREMENTS

Financial Instruments

The financial instruments recorded in our Consolidated Balance Sheets include cash at bank and on-hand (including money market funds and time deposits), restricted cash at bank and on-hand, accounts receivable, marketable securities, equity and cost method investments, accounts payable and accrued expenses, acquisition-related contingent consideration and debt obligations. Included in cash at bank and on-hand and restricted cash at bank and on-hand are money market funds representing a type of mutual fund required by law to invest in low-risk securities (for example, U.S. government bonds, U.S. Treasury Bills and commercial paper). Money market funds pay dividends that generally reflect short-term interest rates. Due to their short-term maturity, the carrying amounts of non-restricted and restricted cash at bank and on-hand (including money market funds and time deposits), accounts receivable, accounts payable and accrued expenses approximate their fair values.

The following table presents current and non-current restricted cash at bank and on-hand balances at December 31, 2018 and 2017 (in thousands):

	2018	2017
Restricted cash at bank and on-hand—current portion (1)	$ 305,368	$ 320,453
Restricted cash at bank and on-hand—noncurrent portion (2)	22,356	3,956
Restricted cash at bank and on-hand—total (3)	$ 327,724	$ 324,409

(1) These amounts are reported in our Consolidated Balance Sheets as Restricted cash at bank and on-hand.
(2) These amounts are reported in our Consolidated Balance Sheets as Other assets.
(3) Approximately $299.7 million and $313.8 million of our restricted cash at bank and on-hand are held in qualified settlement funds (QSFs) for mesh-related matters at December 31, 2018 and December 31, 2017, respectively. The remaining amount of restricted cash at bank and on-hand at December 31, 2018 primarily relates to other litigation-related matters. See Note 13. Commitments and Contingencies for further information.

Fair value guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Marketable Securities

Equity securities consist of investments in the stock of publicly traded companies, the values of which are based on quoted market prices and thus represent Level 1 measurements within the above-defined fair value hierarchy. These securities are not held to support current operations and are therefore classified as non-current assets. Equity securities are included in Marketable securities in our Consolidated Balance Sheets at December 31, 2018 and December 31, 2017.

Acquisition-Related Contingent Consideration

The fair value of contingent consideration liabilities is determined using unobservable inputs; hence these instruments represent Level 3 measurements within the above-defined fair value hierarchy. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at current fair value with changes recorded in earnings. Changes in any of these estimated inputs used as of the date of this report could have resulted in significant adjustments to fair value. See Recurring Fair Value Measurements below for additional information on acquisition-related contingent consideration.

Recurring Fair Value Measurements

The Group's financial assets and liabilities measured at fair value on a recurring basis at December 31, 2018 and 2017 were as follows (in thousands):

	Fair Value Measurements at December 31, 2018 using:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 137,215	$ —	$ —	$ 137,215
Equity securities	738	—	—	738
Total	$ 137,953	$ —	$ —	$ 137,953
Liabilities:				
Acquisition-related contingent consideration—short-term	$ —	$ —	$ 36,514	$ 36,514
Acquisition-related contingent consideration—long-term	—	—	80,189	80,189
Total	$ —	$ —	$ 116,703	$ 116,703

	Fair Value Measurements at December 31, 2017 using:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 439,831	$ —	$ —	$ 439,831
Time deposits	—	303,410	—	303,410
Equity securities	1,456	—	—	1,456
Total	$ 441,287	$ 303,410	$ —	$ 744,697
Liabilities:				
Acquisition-related contingent consideration—short-term	$ —	$ —	$ 70,543	$ 70,543
Acquisition-related contingent consideration—long-term	—	—	119,899	119,899
Total	$ —	$ —	$ 190,442	$ 190,442

At December 31, 2018 and December 31, 2017, money market funds include $86.9 million and $35.6 million, respectively, in QSFs to be disbursed to mesh-related or other product liability claimants. Amounts in QSFs are considered restricted cash equivalents. See Note 13. Commitments and Contingencies for further discussion of our product liability cases. At December 31, 2018 and December 31, 2017, the differences between the amortized cost and the fair value of our money market funds and equity securities, as well as the related gross unrealized gains or losses, were not material, individually or in the aggregate.

Fair Value Measurements Using Significant Unobservable Inputs

The following table presents changes to the Group's liability for acquisition-related contingent consideration, which was measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Beginning of period	$ 190,442	$ 262,113
Amounts settled	(92,627)	(122,559)
Changes in fair value recorded in earnings	19,910	49,949
Effect of currency translation	(1,022)	939
End of period	$ 116,703	$ 190,442

At December 31, 2018, the fair value measurements of the contingent consideration obligations were determined using risk-adjusted discount rates ranging from approximately 9.5% to 17.0% (weighted average rate of approximately 13.2%). Changes in fair value recorded in earnings related to acquisition-related contingent consideration are included in our Consolidated Profit and Loss Account as Acquisition-related and integration items, and amounts recorded for the short-term and long-term portions of acquisition-related contingent consideration are included in Accounts payable and accrued expenses and Other liabilities, respectively, in our Consolidated Balance Sheets.

The following table presents changes to the Group's liability for acquisition-related contingent consideration during the year ended December 31, 2018 by acquisition (in thousands):

	Balance as of December 31, 2017	Fair Value Adjustments and Accretion	Payments and Other	Balance as of December 31, 2018
Auxilium acquisition	$ 13,061	$ 2,941	$ (1,845)	$ 14,157
Lehigh Valley Technologies, Inc. acquisitions	63,001	19,146	(47,447)	34,700
VOLTAREN® Gel acquisition	98,124	9	(41,893)	56,240
Other	16,256	(2,186)	(2,464)	11,606
Total	$ 190,442	$ 19,910	$ (93,649)	$ 116,703

The following table presents changes to the Group's liability for acquisition-related contingent consideration during the year ended December 31, 2017 by acquisition (in thousands):

	Balance as of December 31, 2016	Fair Value Adjustments and Accretion	Payments and Other	Balance as of December 31, 2017
Auxilium acquisition	$ 21,097	$ 467	$ (8,503)	$ 13,061
Lehigh Valley Technologies, Inc. acquisitions	96,000	40,016	(73,015)	63,001
VOLTAREN® Gel acquisition	118,395	18,586	(38,857)	98,124
Other	26,621	(9,120)	(1,245)	16,256
Total	$ 262,113	$ 49,949	$ (121,620)	$ 190,442

Nonrecurring Fair Value Measurements

The Group's financial assets and liabilities measured at fair value on a nonrecurring basis during the years ended December 31, 2018 and 2017 were as follows (in thousands):

	Fair Value Measurements during the Year Ended December 31, 2018 (1) using:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Expense for the Year Ended December 31, 2018
Assets:				
Intangible assets, excluding goodwill (Note 10)	$ —	$ —	$ 239,857	$ (230,418)
Certain tangible fixed assets (2)	—	—	—	(6,521)
Total	$ —	$ —	$ 239,857	$ (236,939)

	Fair Value Measurements during the Year Ended December 31, 2017 (1) using:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Expense for the Year Ended December 31, 2017
Assets:				
Intangible assets, excluding goodwill (Note 10)	$ —	$ —	$ 423,258	$ (799,957)
Certain tangible fixed assets (2)	—	—	—	(65,676)
Total	$ —	$ —	$ 423,258	$ (865,633)

(1) The fair value amounts are presented as of the date of the fair value measurement as these assets are not measured at fair value on a recurring basis. Such measurements generally occur in connection with our quarter-end financial reporting close procedures.

(2) Amount in 2018 includes $2.6 million related to the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative, which is described further in Note 4. Restructuring. Amount in 2017 relates primarily to an aggregate charge of $47.2 million recorded in connection with the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative, which is described further in Note 4. Restructuring, and $11.9 million recorded following the initiation of held-for-sale accounting resulting from the Group's June 30, 2017 definitive agreement to sell Somar, which is described in Note 3. Discontinued Operations and Divestitures.

Additionally, the Group recorded aggregate pre-tax non-cash goodwill impairment charges during the years ended December 31, 2018 and 2017 of $680.0 million and $288.7 million, respectively. Refer to Note 9. Goodwill and Other Intangibless for further description, including the valuation methodologies utilized.

NOTE 7. STOCK

Stock consists of the following at December 31, 2018 and December 31, 2017 (in thousands):

	December 31, 2018	December 31, 2017
Raw materials (1)	$ 122,825	$ 124,685
Work-in-process (1)	70,458	109,897
Finished goods (1)	128,896	156,855
Total	$ 322,179	$ 391,437

(1) The components of stock shown in the table above are net of allowance for obsolescence.

Stock that is in excess of the amount expected to be sold within one year is classified as long-term stock and is not included in the table above. At December 31, 2018 and December 31, 2017, $8.1 million and $17.1 million, respectively, of long-term stock was included in Other assets in the Consolidated Balance Sheets. As of December 31, 2018 and December 31, 2017, the Group's Consolidated Balance Sheets included approximately $12.5 million and $5.9 million, respectively, of capitalized pre-launch stock related to generic products that were not yet available to be sold.

As of December 31, 2018 and 2017, $31.2 million and $46.3 million, respectively, of employee costs were capitalized as part of stock.

NOTE 8. TANGIBLE FIXED ASSETS

Changes in the amount of Tangible fixed assets for the year ended December 31, 2018 are set forth in the table below (in thousands):

Cost:	Land and Buildings	Machinery and Equipment	Leasehold Improvements	Computer Equipment and Software	Assets under Capital Lease	Furniture and Fixtures	Assets under Construction	Total
At January 1, 2018	$ 331,466	$ 267,818	$ 60,464	$ 131,451	$ 4,896	$ 13,124	$ 119,035	$ 928,254
Additions	20,317	34,570	12,925	18,660	2,286	490	5,549	94,797
Disposals, transfers, impairments and other	(126,961)	(90,795)	(4,030)	(32,602)	(1,969)	(1,101)	(3,545)	(261,003)
Effect of currency translation	—	(102)	(103)	(375)	—	(18)	(15)	(613)
At December 31, 2018	$ 224,822	$ 211,491	$ 69,256	$ 117,134	$ 5,213	$ 12,495	$ 121,024	$ 761,435
Accumulated Depreciation:								
At January 1, 2018	$ (149,402)	$ (134,741)	$ (26,867)	$ (82,792)	$ (4,161)	$ (6,320)	$ —	$ (404,283)
Additions	(39,253)	(32,273)	(6,583)	(21,105)	(670)	(1,484)	—	(101,368)
Disposals, transfers and other	121,861	83,037	2,806	32,235	1,969	842	—	242,750
Effect of currency translation	—	71	44	225	—	18	—	358
At December 31, 2018	$ (66,794)	$ (83,906)	$ (30,600)	$ (71,437)	$ (2,862)	$ (6,944)	$ —	$ (262,543)
Net Book Amount:								
At December 31, 2018	$ 158,028	$ 127,585	$ 38,656	$ 45,697	$ 2,351	$ 5,551	$ 121,024	$ 498,892
At December 31, 2017	$ 182,064	$ 133,077	$ 33,597	$ 48,659	$ 735	$ 6,804	$ 119,035	$ 523,971

Depreciation expense, including expense related to assets under capital lease, was $101.4 million and $210.0 million for the years ended December 31, 2018 and 2017, respectively.

During the years ended December 31, 2018 and 2017, the Group recorded impairment charges totaling $6.5 million and $65.7 million, respectively. These charges are included in the Asset impairment charges line item in our Consolidated Profit and Loss Account.

In 2018, impairment charges reflect the write-off of certain tangible fixed assets, including amounts that were abandoned or sold as part of our ongoing efforts to improve our operating efficiency and consolidate certain locations.

In 2017, charges primarily relate to an aggregate charge of $47.2 million recorded in connection with the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative, which is described further in Note 4. Restructuring, and $11.9 million recorded following the initiation of held-for-sale accounting resulting from the Group's June 30, 2017 definitive agreement to sell Somar, which is described in Note 3. Discontinued Operations and Divestitures.

NOTE 9. GOODWILL AND OTHER INTANGIBLES

Goodwill and intangible assets consist of the following:

	Goodwill	In-process Research and Development	Licenses	Tradenames	Developed Technology	Total
	(In thousands)					
Cost:						
At January 1, 2018	$ 5,230,964	$ 347,200	$ 457,402	$ 6,409	$ 6,187,764	$ 12,229,739
Additions	—	—	—	—	3,000	3,000
Impairments	(680,000)	(87,900)	—	—	(142,518)	(910,418)
Other (1)	—	(165,400)	—	—	154,753	(10,647)
Effect of currency translations	(43,583)	—	—	—	(20,984)	(64,567)
At December 31, 2018	$ 4,507,381	$ 93,900	$ 457,402	$ 6,409	$ 6,182,015	$ 11,247,107
Accumulated Amortization:						
At January 1, 2018	$ (780,882)	$ —	$ (370,221)	$ (6,409)	$ (2,304,461)	$ (3,461,973)
Charge	—	—	(27,961)	—	(594,378)	(622,339)
Other (1)	—	—	—	—	10,647	10,647
Effect of currency translations	38,137	—	—	—	10,363	48,500
At December 31, 2018	$ (742,745)	$ —	$ (398,182)	$ (6,409)	$ (2,877,829)	$ (4,025,165)
Net Book Amount:						
At December 31, 2018	$ 3,764,636	$ 93,900	$ 59,220	$ —	$ 3,304,186	$ 7,221,942
At January 1, 2018	$ 4,450,082	$ 347,200	$ 87,181	$ —	$ 3,883,303	$ 8,767,766

(1) Includes reclassification adjustments of $165.4 million for certain developed technology intangible assets, previously classified as in-process research and development, that were placed in service during the year ended December 31, 2018 and the removal of certain fully amortized intangible assets.

Amortization expense for the years ended December 31, 2018 and 2017 totaled $622.3 million and $773.8 million, respectively. Amortization expense is included in Cost of sales in the Consolidated Profit and Loss Account. Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2018 is as follows (in thousands):

2019	$ 550,574
2020	$ 479,358
2021	$ 445,215
2022	$ 418,844
2023	$ 384,223

Impairments

Endo tests goodwill and indefinite-lived intangible assets for impairment annually, or more frequently whenever events or changes in circumstances indicate that the asset might be impaired. Our annual assessment is performed as of October 1st.

As part of our goodwill and intangible asset impairment assessments, we estimate the fair values of our reporting units and our intangible assets using an income approach that utilizes a discounted cash flow model or, where appropriate, a market approach. The discounted cash flow models are dependent upon our estimates of future cash flows and other factors. These estimates of future cash flows involve assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, tax rates, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The discount rates applied to the estimated cash flows for the Group's October 1, 2018 and 2017 annual goodwill and indefinite-lived intangible assets impairment test ranged from 9.5% to 11.5% and from 9.5% to 12.5%, respectively, depending on the overall risk associated with the particular assets and other market factors. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use. Any impairment charges resulting from annual or interim goodwill and intangible asset impairment assessments are recorded to Asset impairment charges in our Consolidated Profit and Loss Account.

During the years ended December 31, 2018 and 2017, the Group incurred the following goodwill and other intangible asset impairment charges (in thousands):

	2018	2017
Goodwill impairment charges	$ 680,000	$ 288,745
Other intangible asset impairment charges	$ 230,418	$ 799,955

A summary of significant goodwill and other intangible asset impairment tests and related charges is included below. Other pre-tax non-cash intangible asset impairment charges that are not included in the below narrative totaled $230.4 million and $586.9 million during the years ended December 31, 2018 and 2017, respectively. These charges relate primarily to certain in-process research and development and/or developed technology intangible assets that were tested for impairment following changes in market conditions and certain other factors impacting recoverability.

Annual Goodwill Impairment Tests

As a result of our annual test performed as of October 1, 2018, the Group determined that the estimated carrying amounts of the U.S. Generic Pharmaceuticals and Paladin reporting units exceeded their respective fair values; therefore, the Group recorded pre-tax non-cash goodwill impairment charges of $258.0 million and $31.0 million, respectively, during the fourth quarter of 2018.

The U.S. Generic Pharmaceuticals impairment can be primarily attributed to an increase in the discount rate used in the determination of fair value and unfavorable underlying business outlook assumption changes. The Paladin impairment was primarily a result of increased competition and slower than expected product launches in our Canadian market. We did not record goodwill impairment charges for the other reporting units as a result of the annual tests.

As a result of our annual test performed as of October 1, 2017, the Group determined that the estimated fair values of its Branded, Generics and Paladin reporting units exceeded their carrying amounts; therefore, no related goodwill impairment charge was required.

Other Impairment Tests

Our first quarter 2018 change in segments described in Note 5. Segment Results resulted in changes to our reporting units for goodwill impairment testing purposes, including the creation of a new U.S. Branded - Sterile Injectables reporting unit, which was previously part of our Generics reporting unit. As a result of these changes, under U.S. GAAP, we tested the goodwill of the former Generics reporting unit immediately before the segment realignment and the goodwill of both the new U.S. Branded - Sterile Injectables and U.S. Generic Pharmaceuticals reporting units immediately after the segment realignment. These goodwill tests were performed using an income approach that utilizes a discounted cash flow model. The results of these goodwill impairment tests were as follows:

- The former Generics reporting unit's estimated fair value (determined using a discount rate of 9.5%) exceeded its carrying amount, resulting in no related goodwill impairment charge.
- The new U.S. Branded - Sterile Injectables reporting unit's estimated fair value (determined using a discount rate of 9.5%) exceeded its carrying amount, resulting in no related goodwill impairment charge.
- The new U.S. Generic Pharmaceuticals reporting unit's carrying amount exceeded its estimated fair value (determined using a discount rate of 9.5%), resulting in a pre-tax non-cash goodwill impairment charge of $391.0 million.

In March 2017, we announced that the FDA's Drug Safety and Risk Management and Anesthetic and Analgesic Drug Products Advisory Committees voted that the benefits of reformulated OPANA® ER (oxymorphone hydrochloride extended release) no longer outweigh its risks. In June 2017, we became aware of the FDA's request that we voluntarily withdraw OPANA® ER from the market and, in July 2017, after careful consideration and consultation with the FDA, we decided to voluntarily remove OPANA® ER from the market. As a result of our decision, the Group determined that the carrying amount of its OPANA® ER intangible asset was no longer recoverable, resulting in a pre-tax, non-cash impairment charge of $20.6 million in the second quarter of 2017, representing the remaining carrying amount.

As a result of the withdrawal of OPANA® ER from the market and the continued erosion of our U.S. Branded - Specialty & Established Pharmaceuticals segment's Established Products portfolio, we initiated an interim goodwill impairment analysis of our Branded reporting unit during the second quarter of 2017. We recorded a pre-tax, non-cash goodwill impairment charge of $180.4 million during the three months ended June 30, 2017 for the amount by which the reporting unit's carrying amount exceeded its fair value. We estimated the fair value of the Branded reporting unit using an income approach that utilized a discounted cash flow model. The discount rate applied to the estimated cash flows for our Branded goodwill impairment test was 9.5%.

Following the announcement of the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative, which is further described in Note 4. Restructuring, the Group assessed the recoverability of certain products that were discontinued as part of this initiative, resulting in pre-tax, non-cash intangible asset impairment charges of approximately $57.5 million during the second quarter of 2017.

Pursuant to an existing agreement with a wholly owned subsidiary of Novartis AG (Novartis), Paladin licensed the Canadian rights to commercialize serelaxin, an investigational drug for the treatment of acute heart failure (AHF). In March 2017, Novartis announced that a Phase 3 study of serelaxin in patients with AHF failed to meet its primary endpoints. As a result, we concluded that the full carrying amount of our serelaxin in-process research and development intangible asset was impaired, resulting in a $45.5 million pre-tax non-cash impairment charge during the three months ended March 31, 2017. In addition, and as a result of the serelaxin impairment, we assessed the recoverability of our Paladin goodwill balance and determined that the estimated fair value of the Paladin reporting unit was below its carrying amount. We recorded a pre-tax, non-cash goodwill impairment charge of $82.6 million during the three months ended March 31, 2017 for the amount by which the carrying amount exceeded the reporting unit's fair value. We estimated the fair value of the Paladin reporting unit using an income approach that utilized a discounted cash flow model. The discount rate applied to the estimated cash flows for our Paladin goodwill impairment test was 10.0%.

As further discussed in Note 3. Discontinued Operations and Divestitures, we entered into a definitive agreement to sell Somar on June 30, 2017, which resulted in Somar's assets and liabilities being classified as held for sale. The initiation of held-for-sale accounting, together with the agreed upon sale price, triggered an impairment review. Accordingly, we performed an impairment analysis using a market approach and determined that impairment charges were required. We recorded pre-tax, non-cash impairment charges of $25.7 million and $89.5 million related to Somar's goodwill and other intangible assets, respectively, during the second quarter of 2017, each of which represented the remaining carrying amounts of the corresponding assets.

NOTE 10. LICENSE AND COLLABORATION AGREEMENTS

Our subsidiaries have entered into certain license, collaboration and discovery agreements with third parties for product development. These agreements require our subsidiaries to share in the development costs of such products and the third parties grant marketing rights to our subsidiaries for such products.

Generally, under these agreements: (i) we are required to make upfront payments and other payments upon successful completion of regulatory or sales milestones and (ii) we are required to pay royalties on sales of the products arising from these agreements.

BioSpecifics Technologies Corp.

The Group, through an affiliate, is party to a development and license agreement, as amended (the BioSpecifics Agreement) with BioSpecifics Technologies Corp. (BioSpecifics). The BioSpecifics Agreement was originally entered into in June 2004 to obtain exclusive worldwide rights to develop, market and sell certain products containing BioSpecifics' enzyme CCH, which we market for approved indications under the trademark XIAFLEX®. The Group's licensed rights concern the development and commercialization of products, other than dermal formulations labeled for topical administration, and currently, the Group's licensed rights cover the indications of Dupuytren's contracture (DC), Dupuytren's nodules, Peyronie's disease (PD), adhesive capsulitis, cellulite, canine and human lipomas, plantar fibromatosis, lateral hip fat and other potential aesthetic indications. The Group may further expand the BioSpecifics Agreement, at its option, to cover other indications as they are developed by the Group or BioSpecifics.

Under the BioSpecifics Agreement, we are responsible, at our own cost and expense, for developing the formulation and finished dosage form of products and arranging for the clinical supply of products. BioSpecifics is currently conducting exploratory clinical trials evaluating CCH as a treatment for a number of conditions, including uterine fibroids. The Group has the option to license development and marketing rights to these indications based on a full analysis of the data from the clinical trials, which would transfer responsibility for the future development costs to the Group and trigger opt-in payments and potential future milestone and royalty payments to BioSpecifics.

The BioSpecifics Agreement extends, on a country-by-country and product-by-product basis, for the longer of the patent life, the expiration of any regulatory exclusivity period or twelve years from the effective date. Either party may terminate the BioSpecifics Agreement as a result of the other party's breach or bankruptcy. We may terminate the BioSpecifics Agreement with 90 days' written notice.

We must pay BioSpecifics on a country-by-country and product-by-product basis a specified percentage within a range of 5% to 15% of net sales for products covered by the BioSpecifics Agreement. This royalty applies to net sales by the Group or its sublicensees, including Asahi Kasei Pharma Corporation and Swedish Orphan Biovitrum AB. We are also obligated to pay a percentage of any future regulatory or commercial milestone payments received from such sublicensees. In addition, the Group and its affiliates pay BioSpecifics an amount equal to a specified mark-up on certain cost of goods related to supply of XIAFLEX® (which mark-up is capped at a specified percentage within the range of 5% to 15% of the cost of goods of XIAFLEX®) for products sold by the Group and its affiliates.

Other

During the second quarter of 2018, we entered into a development, license and commercialization agreement with a third party pharmaceutical company related to five sterile injectable product candidates. Pursuant to this agreement, the third party will generally be responsible, at its expense, to develop and seek regulatory approval for these product candidates, and the Group will generally be responsible, at its expense, to launch and distribute any products that are approved. The Group will have exclusive license rights to all of these products launched in the U.S. and a first right of refusal for the Canadian territory. Upon entering into this agreement, the Group became obligated to make an upfront payment, which was recorded as Research and development expense in the Consolidated Profit and Loss Account during the three months ended June 30, 2018. The Group could become obligated to make additional payments based on certain potential future milestones being achieved.

NOTE 11. CONTRACT ASSETS AND LIABILITIES

Our turnover consists almost entirely of sales of our pharmaceutical products to customers, whereby we ship products to a customer pursuant to a purchase order. Turnover contracts such as these do not generally give rise to contract assets or contract liabilities because: (i) the underlying contracts generally have only a single performance obligation and (ii) we do not generally receive consideration until the performance obligation is fully satisfied. At December 31, 2018, the unfulfilled performance obligations for these types of contracts relate to ordered but undelivered products. We generally expect to fulfill the performance obligations and recognize turnover within one week of entering into the underlying contract. Based on the short-term initial contract duration, additional disclosure about the remaining performance obligations is not required.

Certain of our other turnover-generating contracts, including license and collaboration agreements, may result in contract assets and/or contract liabilities. For example, we may recognize contract liabilities upon receipt of certain upfront and milestone payments from customers when there are remaining performance obligations.

The following table shows the opening and closing balances of contract assets and contract liabilities from contracts with customers (dollars in thousands):

	December 31, 2018	January 1, 2018	$ Change	% Change
Contract assets, net (1)	$ 12,065	$ 11,287	$ 778	7 %
Contract liabilities, net (2)	$ 19,217	$ 20,954	$ (1,737)	(8)%

(1) At December 31, 2018 and January 1, 2018, approximately $9.3 million and $8.2 million, respectively, of these contract asset amounts are classified as current assets and are included in Prepaid expenses and other current assets in the Group's Consolidated Balance Sheets. The remaining amounts are classified as non-current and are included in Other assets. The net increase in contract assets during the year ended December 31, 2018 was primarily due to certain sales activity during the period, partially offset by reclassifications to accounts receivable following the resolution of certain conditions other than the passage of time affecting the Group's rights to consideration for the sale of certain goods.

(2) At December 31, 2018 and January 1, 2018, approximately $1.7 million and $1.9 million, respectively, of these contract liability amounts are classified as current liabilities and are included in Accounts payable and accrued expenses in the Group's Consolidated Balance Sheets. The remaining amounts are classified as non-current and are included in Other liabilities. During the year ended December 31, 2018, the Group recognized turnover of $1.7 million that was included in the contract liability balance at January 1, 2018, resulting in a corresponding decrease in contract liabilities.

During the year ended December 31, 2018, we recognized turnover of $2.8 million relating to performance obligations satisfied, or partially satisfied, in prior periods. Such turnover generally relates to changes in estimates with respect to our variable consideration.

NOTE 12. DEBT

The following table presents information about the Group's total indebtedness at December 31, 2018 and December 31, 2017 (dollars in thousands):

	December 31, 2018			December 31, 2017		
	Effective Interest Rate	Principal Amount	Carrying Amount	Effective Interest Rate	Principal Amount	Carrying Amount
7.25% Senior Notes due 2022	7.91%	$ 400,000	$ 392,947	7.91%	$ 400,000	$ 390,974
5.75% Senior Notes due 2022	6.04%	700,000	694,464	6.04%	700,000	692,855
5.375% Senior Notes due 2023	5.62%	750,000	743,438	5.62%	750,000	742,048
6.00% Senior Notes due 2023	6.28%	1,635,000	1,616,817	6.28%	1,635,000	1,613,446
5.875% Senior Secured Notes due 2024	6.14%	300,000	296,062	6.14%	300,000	295,513
6.00% Senior Notes due 2025	6.27%	1,200,000	1,183,415	6.27%	1,200,000	1,181,243
Term Loan B Facility Due 2024	7.02%	3,363,775	3,331,276	6.09%	3,397,925	3,360,103
Other debt		—	—	1.50%	55	55
Total long-term debt, net		$ 8,348,775	$ 8,258,419		$ 8,382,980	$ 8,276,237
Less current portion, net		34,150	34,150		34,205	34,205
Total long-term debt, less current portion, net		$ 8,314,625	$ 8,224,269		$ 8,348,775	$ 8,242,032

The obligations of the borrowers under the credit agreement are guaranteed by the Group and the subsidiaries of the Group (with certain customary exceptions). The unsecured senior notes are issued by certain of the Group's subsidiaries and are guaranteed on a senior unsecured basis by the subsidiaries of Endo International plc that also guarantee the credit agreement, except for a de minimis amount of the 7.25% Senior Notes due 2022, which are issued by Endo Health Solutions Inc. (EHSI) and guaranteed on a senior unsecured basis by the guarantors named in the Fifth Supplemental Indenture relating to such notes. The senior secured notes are issued by certain of the Group's subsidiaries and are guaranteed on a senior secured basis by Endo International plc and its subsidiaries that also guarantee the credit agreement. The obligations under (i) the credit agreement and related loan documents and (ii) the senior secured notes are secured on a *pari passu* basis by a perfected first priority (subject to certain permitted liens) lien on the collateral securing such instruments, which collateral represents substantially all of the assets of the issuers or borrowers and the guarantors party thereto (subject to customary exceptions). Our senior unsecured notes are unsecured and effectively subordinated in right of priority to our credit agreement and our senior secured notes, in each case to the extent of the value of the collateral securing such instruments.

The aggregate estimated fair value of the Group's long-term debt, which was estimated using inputs based on quoted market prices for the same or similar debt issuances, was $7.2 billion and $7.5 billion at December 31, 2018 and December 31, 2017, respectively. Based on this valuation methodology, we determined these debt instruments represent Level 2 measurements within the fair value hierarchy.

Credit Facilities

The Group and certain of its subsidiaries are party to a credit agreement (the Credit Agreement), which provides for (i) a senior secured revolving credit facility generally allowing for borrowings in a principal amount of up to $1,000.0 million (the Revolving Credit Facility) and (ii) a senior secured term loan facility in an initial principal amount of $3,415.0 million (the Term Loan Facility and, together with the Revolving Credit Facility, the Credit Facilities). We have $997.3 million of remaining credit available through the Revolving Credit Facility at December 31, 2018.

The Credit Agreement contains affirmative and negative covenants that the Group believes to be usual and customary for a senior secured credit facility of this type. The negative covenants include, among other things, limitations on asset sales, mergers and acquisitions, indebtedness, liens, dividends and other restricted payments, investments and transactions with the Group's affiliates. As of December 31, 2018 and 2017, we were in compliance with all such covenants.

The Revolving Credit Facility generally matures in 2022. Principal payments on the Term Loan Facility equal to 0.25% of the initial principal amount are generally payable quarterly until the Term Loan Facility's maturity date in 2024. However, on an annual basis commencing with the year ended December 31, 2018, the Group is required to perform a calculation of Excess Cash Flow (as defined in the Credit Agreement), which could result in certain pre-payments of the principal relating to the Term Loan Facility in accordance with the terms of the Credit Agreement. No such payment is required at December 31, 2018. In addition, any outstanding amounts borrowed pursuant to the Credit Facilities will immediately mature if any of the following of our senior notes (other than, in the case of amounts borrowed pursuant to the Revolving Credit Facility, the 5.375% Senior notes due 2023 and the 6.00% Senior Notes due 2023) are not refinanced or repaid in full prior to the date that is 91 days prior to the stated maturity date thereof:

Instrument	Maturity Date
7.25% Senior Notes Due 2022	January 15, 2022
5.75% Senior Notes Due 2022	January 15, 2022
5.375% Senior Notes Due 2023	January 15, 2023
6.00% Senior Notes Due 2023	July 15, 2023

The Credit Agreement provides that the borrowers thereunder may incur (i) incremental revolving commitments and/or incremental term loans in an aggregate principal amount of up to: (a) up to $1.0 billion plus (b) an unlimited amount if the *pro forma* First Lien Net Leverage Ratio (as defined in the Credit Agreement) at the time of incurrence of such incremental commitments or loans after giving effect thereto is less than or equal to 2.50 to 1.00 (assuming for purposes of such calculation that any incremental revolving commitments being incurred are fully drawn and without netting cash proceeds of any incremental facilities or incremental equivalent debt) or, (ii) in lieu of incremental facilities under the Credit Agreement, incremental equivalent debt consisting of *pari passu* notes or loans (subject to *pro forma* compliance with a First Lien Net Leverage Ratio of 2.50 to 1.00), junior secured notes or loans (subject to *pro forma* compliance with a Secured Net Leverage Ratio (as defined in the Credit Agreement) of 3.50 to 1.00) or unsecured notes or loans (subject to *pro forma* compliance with a Total Net Leverage Ratio (as defined in the Credit Agreement) of 6.50 to 1.00), subject, in each case, to compliance by the borrowers with the documentation and other requirements under the Credit Agreement, without the need for consent from any of the existing lenders under the Credit Agreement.

Borrowings under the Revolving Credit Facility bear interest, at the borrower's election, at a rate equal to (i) an applicable margin between 1.50% and 3.00% depending on the Group's Total Net Leverage Ratio plus the London Interbank Offered Rate (LIBOR) or (ii) an applicable margin between 0.50% and 2.00% depending on the Group's Total Net Leverage Ratio plus the Alternate Base Rate (as defined in the Credit Agreement). In addition, borrowings under our Term Loan Facility bear interest, at the borrower's election, at a rate equal to (i) 4.25% plus LIBOR, subject to a LIBOR floor of 0.75%, or (ii) 3.75% plus the Alternate Base Rate, subject to an Alternate Base Rate floor of 1.75%.

Senior Notes and Senior Secured Notes

Our various senior notes and senior secured notes mature between 2022 and 2025. The indentures governing these notes generally allow for redemption prior to maturity, in whole or in part, subject to certain restrictions and limitations described therein, in the following ways:

- Until a date specified in each indenture (the Non-Call Period), the notes may be redeemed, in part or in full, by paying the sum of: (i) 100% of the principal amount being redeemed, (ii) an applicable make-whole premium as described in each indenture and (iii) accrued and unpaid interest. As of December 31, 2018, the Non-Call Period has expired for each of our notes except for the 5.875% Senior Secured Notes due 2024 (the 2024 Notes) and the 6.00% Senior Notes due 2025.
- After the Non-Call Period specified in each indenture, the notes may be redeemed, in whole or in part, at redemption prices set forth in each indenture, plus accrued and unpaid interest. The redemption prices for each of our notes vary over time. The redemption prices pursuant to this clause range from 101.208% to 104.500% of principal at December 31, 2018; however, these redemption prices generally decrease to 100% of the principal amount of the applicable notes over time as the notes approach maturity pursuant to a step-down schedule set forth in each of the indentures.
- Until a date specified in each indenture, the notes may be redeemed, in part (up to 35% of the principal amount outstanding) with the net cash proceeds from specified equity offerings at redemption prices set forth in each indenture, plus accrued and unpaid interest. As of December 31, 2018, this clause has expired for each of our notes except for the 2024 Notes, for which the specified redemption premium is 105.875%.

Other than the 2024 Notes, these notes are senior unsecured obligations of the Group's subsidiaries party to the applicable indentures governing such notes. These notes are issued by certain of the Group's subsidiaries and are guaranteed on a senior unsecured basis by the subsidiaries of Endo International plc that also guarantee the Credit Agreement, except for a de minimis amount of the 7.25% Senior Notes due 2022, which are issued by EHSI and guaranteed on a senior unsecured basis by the guarantors named in the Fifth Supplemental Indenture relating to such notes. The 2024 Notes are senior secured obligations of Endo International plc and its subsidiaries that are party to the indenture governing such notes. These notes are issued by certain of our subsidiaries and are guaranteed on a senior secured basis by Endo International plc and its subsidiaries that also guarantee our Credit Agreement.

The indentures governing our various senior notes contain affirmative and negative covenants that the Group believes to be usual and customary for similar indentures. Under the senior secured notes indenture, the negative covenants, among other things, restrict the Group's ability, and the ability of its restricted subsidiaries, to incur certain additional indebtedness and issue preferred stock, make certain dividends, distributions, investments and other restricted payments, sell certain assets, enter into sale and leaseback transactions, agree to payment restrictions on the ability of restricted subsidiaries to make certain payments to Endo International plc or any of its restricted subsidiaries, create certain liens, merge, consolidate or sell all or substantially all of the Group's or guarantors' assets, enter into certain transactions with affiliates or designate subsidiaries as unrestricted subsidiaries. Under the senior unsecured notes indentures, the negative covenants, among other things, restrict the ability of Endo Designated Activity Company and its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock, make certain dividends, distributions, investments and other restricted payments, sell certain assets, enter into sale and leaseback transactions, agree to payment restrictions on the ability of restricted subsidiaries to make certain payments to the issuer or any of the restricted subsidiaries, create certain liens, merge, consolidate or sell all or substantially all of Endo Designated Activity Company's, its co-issuers' or guarantors' assets, enter into certain transactions with affiliates or designate subsidiaries as unrestricted subsidiaries. These covenants are subject to a number of exceptions and qualifications, including the fall away or revision of certain of these covenants, and release of collateral in the case of the 2024 Notes, upon the notes receiving investment grade credit ratings. As of December 31, 2018 and 2017, we were in compliance with all such covenants. Additionally, pursuant to the terms of the indentures governing certain of our senior unsecured notes, the restricted subsidiaries of Endo International plc, whose assets comprise substantially all of the Group's consolidated total assets after intercompany eliminations, are subject to various restrictions limiting their ability to transfer assets in excess of certain thresholds to Endo International plc.

April 2017 Refinancing

The Group and/or certain of its subsidiaries entered into the Credit Agreement and issued the 2024 Notes on April 27, 2017 (the April 2017 Refinancing). The Group used the net proceeds under the Term Loan Facility, together with the net proceeds of the 2024 Notes and cash on hand, to refinance certain of its prior indebtedness and to pay related fees and expenses.

In connection with the April 2017 Refinancing, we incurred new debt issuance costs of approximately $56.7 million, which were allocated among the new debt instruments as follows: (i) $41.3 million to the Term Loan Facility, (ii) $10.5 million to the Revolving Credit Facility and (iii) $4.9 million to the 2024 Notes. These costs, together with $10.1 million of the previously deferred debt issuance costs associated with our prior revolving credit facility, were deferred and are being amortized as interest expense over the terms of the respective instruments. The remaining $51.7 million of deferred debt issuance costs associated with our prior revolving and term loan facilities were charged to expense in the second quarter of 2017. These expenses were included in the Consolidated Profit and Loss Account as Loss on extinguishment of debt.

Maturities

The following table presents the maturities on our long-term debt for each of the five fiscal years subsequent to December 31, 2018 (in thousands):

	Maturities (1)
2019	$ 34,150
2020	$ 34,150
2021	$ 34,150
2022	$ 1,134,150
2023	$ 2,419,150

(1) As described above under the heading "Credit Facilities," certain amounts borrowed pursuant to the Credit Facilities will immediately mature if certain of our senior notes are not refinanced or repaid in full prior to the date that is 91 days prior to the respective stated maturity dates thereof. Accordingly, we may be required to repay or refinance senior notes with aggregate principal amounts of $1,100.0 million in 2021, despite such notes having stated maturities in 2022, and/or $750.0 million in 2022, despite such notes having stated maturities in 2023. The amounts in this maturities table do not reflect any such early payment; rather, they reflect stated maturity dates.

NOTE 13. COMMITMENTS AND CONTINGENCIES

Manufacturing, Supply and Other Service Agreements

Our subsidiaries contract with various third party manufacturers, suppliers and service providers to provide raw materials used in our subsidiaries' products and semi-finished and finished goods, as well as certain packaging, labeling services, customer service support, warehouse and distribution services. If, for any reason, we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products or services needed to conduct our business, it could have an adverse effect on our business, financial condition, results of operations and cash flows.

In addition to the manufacturing and supply agreements described above, we have agreements with various companies for clinical development services. Although we have no reason to believe that the parties to these agreements will not meet their obligations, failure by any of these third parties to honor their contractual obligations may have a material adverse effect on our business, financial condition, results of operations and cash flows.

Jubilant HollisterStier Laboratories LLC (JHS)

During the second quarter of 2016, we entered into a new agreement with JHS (the JHS Agreement). Pursuant to the JHS Agreement, JHS fills and lyophilizes the XIAFLEX® bulk drug substance, which is manufactured by the Group, and produces sterile diluent. The initial term of the JHS Agreement is three years, with automatic renewal provisions thereafter for subsequent one-year terms, unless or until either party provides notification prior to expiration of the then current term of the contract. The Group is required to purchase a specified percentage of its total forecasted volume of XIAFLEX® from JHS each year, unless JHS is unable to supply XIAFLEX® within the timeframe established under such forecasts. Amounts purchased pursuant to the JHS Agreement were $7.5 million and $5.6 million for the years ended December 31, 2018 and 2017.

Milestones and Royalties

See Note 10. License and Collaboration Agreements for a description of future milestone and royalty commitments pursuant to our material acquisitions, license and collaboration agreements.

Legal Proceedings and Investigations

We and certain of our subsidiaries are involved in various claims, legal proceedings and internal and governmental investigations (collectively, proceedings) that arise from time to time, including, among others, those relating to product liability, intellectual property, regulatory compliance, consumer protection and commercial matters. While we cannot predict the outcome of these proceedings and we intend to vigorously prosecute or defend our position as appropriate, there can be no assurance that we will be successful or obtain any requested relief, and an adverse outcome in any of these proceedings could have a material adverse effect on our current and future financial position, results of operations and cash flows. Matters that are not being disclosed herein are, in the opinion of our management, immaterial both individually and in the aggregate with respect to our financial position, results of operations and cash flows. If and when such matters, in the opinion of our management, become material, either individually or in the aggregate, we will disclose them.

We believe that certain settlements and judgments, as well as legal defense costs, relating to certain product liability or other matters are or may be covered in whole or in part under our insurance policies with a number of insurance carriers. In certain circumstances, insurance carriers reserve their rights to contest or deny coverage. We intend to contest vigorously any and all disputes with our insurance carriers and to enforce our rights under the terms of our insurance policies. Accordingly, we will record receivables with respect to amounts due under these policies only when the realization of the potential claim for recovery is considered probable. Amounts recovered under our insurance policies could be materially less than the stated coverage limits and may not be adequate to cover damages and/or costs relating to claims. In addition, there is no guarantee that insurers will pay claims or that coverage will otherwise be available.

As of December 31, 2018, our accrual for loss contingencies totaled $955.1 million, of which $748.6 million relates to our liability accrual for vaginal mesh cases and other mesh-related matters. During the fourth quarter of 2017, the Group recorded a total increase to its liability accrual of approximately $200 million related to testosterone-related product liability matters and LIDODERM®-related antitrust matters. The accrual for LIDODERM®-related matters includes an estimated loss for, among other matters, settlement of all remaining claims filed against EPI in multidistrict litigation (MDL) No. 2521 (defined below), which matters are further discussed below under the heading "Other Antitrust Matters." The testosterone-related accrual includes an estimated loss for, among other matters, all testosterone-related product liability cases filed in MDL No. 2545 (defined below) and in other courts. These cases are further discussed below under the heading "Product Liability and Related Matters." Although we believe there is a reasonable possibility that a loss in excess of the amount recognized exists, we are unable to estimate the possible loss or range of loss in excess of the amount recognized at this time.

Product Liability and Related Matters

We and certain of our subsidiaries have been named as defendants in numerous lawsuits in various U.S. federal and state courts, as well as in Canada and other countries, alleging personal injury resulting from the use of certain products of our subsidiaries. These and other related matters are described below in more detail.

Vaginal Mesh. Since 2008, we and certain of our subsidiaries, including American Medical Systems Holdings, Inc. (subsequently converted to Astora Women's Health Holding LLC and merged into Astora Women's Health LLC and referred to herein as AMS) and/or Astora, have been named as defendants in multiple lawsuits in various state and federal courts in the U.S. (including a federal MDL pending in the U.S. District Court for the Southern District of West Virginia (MDL No. 2325)), and in Canada and other countries, alleging personal injury resulting from the use of transvaginal surgical mesh products designed to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). In January 2018, a representative proceeding (class action) was filed in the Federal Court of Australia against American Medical Systems, LLC. In the various class action and individual complaints, plaintiffs claim a variety of personal injuries, including chronic pain, incontinence, inability to control bowel function and permanent deformities, and seek compensatory and punitive damages, where available.

We and certain plaintiffs' counsel representing mesh-related product liability claimants have entered into various Master Settlement Agreements (MSAs) and other agreements to resolve up to approximately 71,000 filed and unfiled mesh claims handled or controlled by the participating counsel. These MSAs and other agreements were entered into at various times between June 2013 and the present, were solely by way of compromise and settlement and were not in any way an admission of liability or fault by us or any of our subsidiaries.

All MSAs are subject to a process that includes guidelines and procedures for administering the settlements and the release of funds. In certain cases, the MSAs provide for the creation of QSFs into which funds may be deposited pursuant to certain schedules set forth in those agreements. All MSAs have participation requirements regarding the claims represented by each law firm party to the MSA. In addition, one agreement gives us a unilateral right of approval regarding which claims may be eligible to participate under that settlement. To the extent fewer claims than are authorized under an agreement participate, the total settlement payment under that agreement will be reduced by an agreed-upon amount for each such non-participating claim. Funds deposited in QSFs are considered restricted cash at bank and in-hand.

Distribution of funds to any individual claimant is conditioned upon the receipt of documentation substantiating the validity of the claim, a full release and dismissal of the entire action or claim as to all AMS parties and affiliates. Prior to receiving funds, an individual claimant is required to represent and warrant that liens, assignment rights or other claims identified in the claims administration process have been or will be satisfied by the individual claimant. Confidentiality provisions apply to the amount of settlement awards to participating claimants, the claims evaluation process and procedures used in conjunction with award distributions, and the negotiations leading to the settlements.

In June 2017, the MDL court entered a case management order which, among other things, requires plaintiffs in newly-filed MDL cases to provide expert disclosures on specific causation within one hundred twenty (120) days of filing a claim (the Order). Under the Order, a plaintiff's failure to meet the foregoing deadline may be grounds for the entry of judgment against such plaintiff. In July 2017, a similar order was entered in Minnesota state court. In June 2018, at the request of the MDL court, the Judicial Panel on Multidistrict Litigation entered a minute order suspending the transfer of cases into the MDL. Subsequently, the MDL court issued a pretrial order discontinuing the direct filing of claims in MDL No. 2325. The MDL court also issued similar orders in other MDLs involving claims against other mesh manufacturers.

Although the Group believes it has appropriately estimated the probable total amount of loss associated with all matters as of the date of this report, fact and expert discovery is ongoing in certain cases that have not settled, and it is reasonably possible that further claims may be filed or asserted and that adjustments to our liability accrual may be required. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The following table presents the changes in the QSFs and mesh liability accrual balances during the year ended December 31, 2018 (in thousands):

	Qualified Settlement Funds	Mesh Liability Accrual
Balance as of January 1, 2018	$ 313,814	$ 1,087,172
Additional charges	—	34,000
Cash contributions to Qualified Settlement Funds	336,648	—
Cash distributions to settle disputes from Qualified Settlement Funds	(353,032)	(353,032)
Cash distributions to settle disputes	—	(25,222)
Other (1)	2,303	5,688
Balance as of December 31, 2018	$ 299,733	$ 748,606

(1) Amounts deposited in the QSFs may earn interest, which is generally used to pay administrative costs of the fund and is reflected in the table above as an increase to the QSF and Mesh Liability Accrual balances. Any interest remaining after all claims have been paid will generally be distributed to the claimants who participated in that settlement. The $5.7 million in the table above also includes a second quarter 2018 reclassification adjustment of $4.4 million for accrued interest amounts previously recorded in Accounts payable and accrued expenses in the Consolidated Balance Sheets.

While the timing of the resolution of certain of the matters included in this mesh liability accrual remains uncertain, as of December 31, 2018, the entire liability accrual amount is classified in the Current portion of the legal settlement accrual in the Consolidated Balance Sheets. Charges related to vaginal mesh liability and associated legal fees and other expenses for all periods presented are reported in Discontinued operations, net of tax in our Consolidated Profit and Loss Account.

As of December 31, 2018, the Group has made total mesh liability payments of approximately $3.3 billion, $299.7 million of which remains in the QSFs as of December 31, 2018. We currently expect to fund into the QSFs the remaining payments under all settlement agreements during 2019. As the funds are disbursed out of the QSFs from time to time, the liability accrual will be reduced accordingly with a corresponding reduction to restricted cash at bank and in-hand. In addition, we may pay cash distributions to settle disputes separate from the QSFs, which will also decrease the liability accrual and decrease cash at bank and in-hand.

We were contacted in October 2012 regarding a civil investigation initiated by various state attorneys general into mesh products, including transvaginal surgical mesh products designed to treat POP and SUI. In November 2013, we received a subpoena relating to this investigation from the state of California, and we have subsequently received additional subpoenas from California and other states. We are cooperating with these investigations.

We will continue to vigorously defend any unresolved claims and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any additional losses that could be incurred.

Testosterone. Various manufacturers of prescription medications containing testosterone, including our subsidiaries Endo Pharmaceuticals Inc. (EPI) and Auxilium Pharmaceuticals, Inc. (subsequently converted to Auxilium Pharmaceuticals, LLC and hereinafter referred to as Auxilium), have been named as defendants in multiple lawsuits alleging personal injury resulting from the use of such medications, including FORTESTA® Gel, DELATESTRYL®, TESTIM®, TESTOPEL®, AVEED® and STRIANT®. Plaintiffs in these suits generally allege various personal injuries, including pulmonary embolism, stroke or other vascular and/or cardiac injuries, and seek compensatory and/or punitive damages, where available.

As of April 17, 2019, we were aware of approximately 954 testosterone cases (some of which may have been filed on behalf of multiple plaintiffs) pending against one or more of our subsidiaries in federal or state court. Most of these cases have been coordinated in a federal MDL pending in the U.S. District Court for the Northern District of Illinois (MDL No. 2545). An MDL trial against Auxilium involving TESTIM® took place in November 2017 and resulted in a defense verdict. A trial against Auxilium involving TESTIM® was scheduled for January 2018 in the Philadelphia Court of Common Pleas but resolved prior to trial.

In June 2018, counsel for plaintiffs, on the one hand, and Auxilium and EPI, on the other, executed an MSA allowing for the resolution of all known testosterone replacement therapy product liability claims against our subsidiaries. The MSA was solely by way of compromise and settlement and was not in any way an admission of fault by us or any of our subsidiaries.

The MSA is subject to a process that includes guidelines and procedures for administering the settlement and the release of funds. Among other things, the MSA provides for the creation of a QSF into which the settlement funds will be deposited, establishes participation requirements and allows for a reduction of the total settlement payment in the event the participation threshold is not met. Distribution of funds to any individual claimant is conditioned upon the receipt of documentation substantiating product use and injury as determined by a third-party special master, the dismissal of any lawsuit and the release of the claim as to us and all affiliates. Prior to receiving funds, an individual claimant must represent and warrant that liens, assignment rights or other claims identified in the claims administration process have been or will be satisfied by the individual claimant. Confidentiality provisions apply to the settlement funds, amounts allocated to individual claimants and other terms of the agreement.

Although the Group believes it has appropriately estimated the probable total amount of loss associated with testosterone-related product liability matters as of the date of this report, it is reasonably possible that further claims may be filed or asserted and that adjustments to our liability accrual may be required. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The MDL also included a lawsuit filed in November 2014 in the U.S. District for the Northern District of Illinois against EPI, Auxilium and various other manufacturers of testosterone products on behalf of a proposed class of health insurance companies and other third party payers that claim to have paid for certain testosterone products. This lawsuit is not part of the settlement described above. After a series of motions to dismiss, plaintiff filed a third amended complaint in April 2016, asserting civil claims for alleged violations of the Racketeer Influenced and Corrupt Organizations Act and negligent misrepresentation based on defendants' marketing of certain testosterone products. The court denied a motion to dismiss this complaint in August 2016. In July 2018, the court denied plaintiff's motion for class certification. In February 2019, the court granted defendants' motion for summary judgment. Plaintiffs have appealed to the U.S. Court of Appeals for the Seventh Circuit.

We will continue to vigorously defend any unresolved claims and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any additional losses that could be incurred.

Opioid-Related Matters

Since 2014, multiple U.S. states, counties, other governmental persons or entities and private plaintiffs have filed suit against us and/or certain of our subsidiaries, including Endo Health Solutions Inc. (EHSI), EPI, Par Pharmaceutical, Inc. (PPI), Par Pharmaceutical Companies, Inc., Vintage Pharmaceuticals, LLC, Generics Bidco I, LLC and DAVA Pharmaceuticals, LLC, as well as various other manufacturers, distributors and/or others, asserting claims relating to defendants' alleged sales, marketing and/or distribution practices with respect to prescription opioid medications, including certain of our products. As of April 17, 2019, the cases of which we were aware include, but are not limited to, approximately 13 cases filed by or on behalf of states; approximately 1,894 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 131 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers and approximately 57 cases filed by individuals. Certain of the cases have been filed as putative class actions. In addition to the litigation in the U.S., in August 2018, an action against Paladin Labs, EPI, the Group and various other manufacturers and distributors was commenced in British Columbia on behalf of all federal, provincial and territorial governments and agencies in Canada that paid healthcare, pharmaceutical and treatment costs related to opioids.

Many of the U.S. cases have been coordinated in a federal MDL pending in the U.S. District Court for the Northern District of Ohio (MDL No. 2804). In March 2018, the U.S. Department of Justice (DOJ) filed a statement of interest in the case, and in April 2018 it filed a motion to participate in settlement discussions as a friend of the court, which the MDL court granted. The MDL court has issued a series of case management orders permitting motions to dismiss addressing threshold legal issues in certain cases (and has issued orders granting in part and denying in part some of those motions), setting a trial date in October 2019 for the claims of two Ohio counties, allowing certain discovery and establishing certain other deadlines and procedures, among other things.

Other cases remain pending in various state courts. In some jurisdictions, such as Connecticut, Illinois, New York, Pennsylvania, South Carolina and Texas, certain state court cases have been transferred to a single court within their respective state court systems for coordinated pretrial proceedings. The state cases are generally at the pleading and/or discovery stage with certain of these cases scheduled for trial beginning in 2020.

The complaints in the cases assert a variety of claims including, but not limited to, claims for alleged violations of public nuisance, consumer protection, unfair trade practices, racketeering, Medicaid fraud and/or drug dealer liability statutes and/or common law claims for public nuisance, fraud/misrepresentation, strict liability, negligence and/or unjust enrichment. The claims are generally based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid medications and/or an alleged failure to take adequate steps to prevent abuse and diversion. Plaintiffs generally seek declaratory and/or injunctive relief; compensatory, punitive and/or treble damages; restitution, disgorgement, civil penalties, abatement, attorneys' fees, costs and/or other relief.

We will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred.

In addition to the lawsuits described above, the Group and/or its subsidiaries have received certain subpoenas, civil investigative demands (CIDs) and informal requests for information concerning the sale, marketing and/or distribution of prescription opioid medications, including the following:

Various state attorneys general have served subpoenas and/or CIDs on EHSI and/or EPI. We are cooperating with these investigations.

In January 2018, our subsidiary EPI received a federal grand jury subpoena from the U.S. District Court for the Southern District of Florida in connection with an investigation being conducted by the U.S. Attorney's Office for the Southern District of Florida in conjunction with the U.S. Food and Drug Administration (FDA). The subpoena seeks information related to OPANA® ER and other oxymorphone products. EPI is cooperating with the investigation.

Similar investigations may be brought by others or the foregoing matters may be expanded or result in litigation. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred.

Generic Drug Pricing Matters

In December 2014, we received a grand jury subpoena from the Antitrust Division of the DOJ issued by the U.S. District Court for the Eastern District of Pennsylvania addressed to Par Pharmaceuticals. The subpoena requested documents and information focused primarily on product and pricing information relating to the authorized generic version of Lanoxin (digoxin) oral tablets and generic doxycycline products, and on communications with competitors and others regarding those products. We are cooperating with the investigation.

In May 2018, we and our subsidiary Par Pharmaceutical Companies, Inc. each received a CID from the DOJ in relation to a False Claims Act investigation concerning whether generic pharmaceutical manufacturers engaged in price-fixing and market allocation agreements, paid illegal remuneration and caused the submission of false claims. We are cooperating with the investigation.

Similar investigations may be brought by others or the foregoing matters may be expanded or result in litigation. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred.

Since March 2016, various private plaintiffs and state attorneys general have filed cases against our subsidiary PPI and/or, in some instances, the Group, Generics Bidco I, LLC, DAVA Pharmaceuticals, LLC and/or Par Pharmaceutical Companies, Inc., as well as other pharmaceutical manufacturers and, in some instances, other corporate and/or individual defendants, alleging price-fixing and other anticompetitive conduct with respect to generic pharmaceutical products. These cases, which include proposed class actions filed on behalf of direct purchasers, end-payers and indirect purchaser resellers, have been consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Eastern District of Pennsylvania under the caption *In re Generic Pharmaceuticals Pricing Antitrust Litigation* (MDL No. 2724).

The various complaints and amended complaints generally assert claims under federal and/or state antitrust law, state consumer protection statutes and/or state common law, and seek damages, treble damages, civil penalties, disgorgement, declaratory and injunctive relief, costs and attorneys' fees. Some claims are based on alleged product-specific conspiracies. With respect to our subsidiaries, the allegations in the various complaints focus on amitriptyline, baclofen, digoxin, divalproex ER, doxycycline hyclate, doxycycline monohydrate, nystatin, propranolol and/or zoledronic acid. Other claims allege broader, multiple-product conspiracies involving various combinations of these and/or other products. Under these overarching conspiracy theories, plaintiffs seek to hold all alleged participants in a particular conspiracy jointly and severally liable for all harms caused by the alleged conspiracy, not just harms related to the products manufactured and/or sold by a particular defendant.

In October 2018, the MDL court denied defendants' motions to dismiss federal antitrust claims relating to digoxin, divalproex ER and doxycycline hyclate, among other products. In February 2019, the MDL court dismissed certain state law claims relating to these same products, but allowed other state law claims relating to those products to proceed. In February 2019, the defendants moved to dismiss plaintiffs' overarching conspiracy claims; that motion remains pending. The MDL court has also allowed certain discovery.

We will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred.

Other Antitrust Matters

Beginning in November 2013, multiple direct and indirect purchasers of LIDODERM® filed a number of cases against our subsidiary EPI and other pharmaceutical companies generally alleging that they had entered into an anticompetitive agreement to restrain trade through the settlement of patent infringement litigation concerning U.S. Patent No. 5,827,529 (the '529 patent) and other patents. The complaints asserted claims under Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1, 2), and/or various state antitrust and consumer protection statutes, as well as common law claims, and generally sought damages, treble damages, disgorgement of profits, restitution, injunctive relief and attorneys' fees. The cases were consolidated and/or coordinated in April 2014 in a federal MDL in the U.S. District Court for the Northern District of California (MDL No. 2521). The MDL court certified classes of direct and indirect purchasers in February 2017. EPI settled with certain opt-out retailer plaintiffs in October 2017. In September 2018, the court approved EPI's settlement with the class plaintiffs and entered judgment dismissing the class cases with prejudice. In connection with the settlements, several indirect purchasers which previously had opted out were permitted to rejoin the class. The class settlement agreements provide for aggregate payments of approximately $100 million. As of April 22, 2019, EPI had paid approximately $90 million of this total, including approximately $60 million in 2018 and $30 million in the first quarter of 2019. The remaining $10 million is included in our accrual for loss contingencies.

Beginning in June 2014, multiple direct and indirect purchasers of OPANA® ER filed cases against our subsidiaries EHSI and EPI and other pharmaceutical companies, including Impax Laboratories, LLC (formerly Impax Laboratories, Inc. and referred to herein as Impax) and Penwest Pharmaceuticals Co., which our subsidiary EPI had acquired. Some cases were filed on behalf of putative classes of direct and indirect purchasers, while others were filed on behalf of individual retailers or health care benefit plans. All cases have been consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Northern District of Illinois (MDL No. 2580). Plaintiffs generally allege that an agreement reached by EPI and Impax to settle patent infringement litigation concerning multiple patents pertaining to OPANA® ER and EPI's introduction of reformulated OPANA® ER violated antitrust laws. The complaints assert claims under Sections 1 and 2 of the Sherman Act, various state antitrust and consumer protection statutes and/or state common law. Plaintiffs generally seek damages, treble damages, disgorgement of profits, restitution, injunctive relief and attorneys' fees. In February 2016, the MDL court issued orders (i) denying defendants' motion to dismiss the claims of the direct purchasers, (ii) denying in part and granting in part defendants' motion to dismiss the claims of the indirect purchasers, but giving them permission to file amended complaints and (iii) granting defendants' motion to dismiss the complaints filed by certain retailers, but giving them permission to file amended complaints. In response to the MDL court's orders, the indirect purchasers filed an amended complaint to which the defendants filed a renewed motion to dismiss certain claims, and certain retailers also filed amended complaints. The court has dismissed the indirect purchaser unjust enrichment claims arising under the laws of the states of California, Rhode Island and Illinois. The cases are currently in expert discovery. In March 2019, direct and indirect purchaser plaintiffs filed motions for class certification. We will continue to vigorously defend these matters and to explore other options as appropriate in our best interests.

Beginning in February 2009, the FTC and certain private plaintiffs, including distributors and retailers, filed suit against our subsidiary Par Pharmaceutical Companies, Inc. (since June 2016, Endo Generics Holdings, Inc., and referred to in this Commitments and Contingencies note as EGHI) and other pharmaceutical companies alleging violations of antitrust law arising out of their settlement of certain patent litigation concerning the generic version of AndroGel®. Generally, the complaints seek damages, treble damages, equitable relief and attorneys' fees and costs. The cases have been consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Northern District of Georgia (MDL No. 2084). In September 2012, the MDL court granted summary judgment to defendants on plaintiffs' claims of sham litigation. In May 2016, plaintiffs representing a putative class of indirect purchasers voluntarily dismissed their claims with prejudice. In February 2017, the FTC voluntarily dismissed its claims against EGHI with prejudice. Claims by certain alleged direct purchasers or their assignees are still pending against EGHI and other defendants. In June 2018, the MDL court granted in part and denied in part various summary judgment and evidentiary motions filed by defendants. In particular, the court rejected two of direct purchasers' three causation theories, rejected damages claims related to AndroGel® 1.62% and granted in part a motion seeking to exclude part of plaintiffs' proposed manufacturing expert's opinions. The motions were denied in all other respects, and the court denied a motion for reconsideration, or in the alternative leave to file an interlocutory appeal, in October 2018. In July 2018, the district court denied certain plaintiffs' motion for certification of a direct purchaser class. The MDL court has scheduled trial for February 2020. We will continue to vigorously defend these matters and to explore other options as appropriate in our best interests.

Beginning in May 2018, multiple alleged direct and indirect purchasers filed complaints in the U.S. District Court for the Southern District of New York against PPI, EPI and/or us, as well as others, alleging a conspiracy to delay generic competition and monopolize the market for Exforge® (amlodipine/valsartan) and its generic equivalents. Some cases were filed on behalf of putative classes of direct and indirect purchasers; others were filed on behalf of individual retailers. The plaintiffs generally assert claims under Sections 1 and 2 of the Sherman Act, various state antitrust and consumer protection statutes and state common law and seek damages, treble damages, equitable relief and attorneys' fees and costs. In September 2018, the putative class plaintiffs stipulated to the dismissal without prejudice of their claims against EPI and us, and the retailer plaintiffs later did the same. PPI filed a partial motion to dismiss certain claims in September 2018. We intend to vigorously defend these matters and to explore other options as appropriate in our best interests.

In November 2014, EPI received a CID from Florida's Office of the Attorney General seeking documents and other information concerning EPI's agreement with Actavis settling the LIDODERM® patent litigation, as well as information concerning marketing and sales of LIDODERM®. EPI and/or EHSI later received similar CIDs from other states. A CID from Alaska's Office of the Attorney General in February 2015 included requests for documents and information concerning agreements with Actavis and Impax settling the OPANA® ER patent litigation. We are cooperating with these investigations.

In February 2015, EGHI and affiliates received a CID from the Office of the Attorney General for the state of Alaska seeking production of certain documents and information regarding EGHI's settlement of the AndroGel® patent litigation as well as documents produced in the aforementioned litigation filed by the FTC. We are cooperating with this investigation.

Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any additional losses that could be incurred.

Securities Litigation

In May 2016, a putative class action entitled *Craig Friedman v. Endo International plc, Rajiv Kanishka Liyanaarchchie de Silva and Suketu P. Upadhyay* was filed in the U.S. District Court for the Southern District of New York by an individual shareholder on behalf of himself and all similarly situated shareholders. In August 2016, the court appointed Steamfitters' Industry Pension Fund and Steamfitters' Industry Security Benefit Fund as lead plaintiffs in the action. In October 2016, plaintiffs filed a second amended complaint that, among other things, added Paul Campanelli as a defendant, and we filed a motion to dismiss. In response, and without resolving the motion, the court permitted lead plaintiffs to file a third amended complaint. The amended complaint alleged violations of Sections 10(b) and 20(a) of the Exchange Act based on the Group's revision of its 2016 earnings guidance and certain disclosures about its generics business, the integration of Par Pharmaceutical Holdings, Inc. and its subsidiaries, certain other alleged business issues and the receipt of a CID from the U.S. Attorney's Office for the Southern District of New York regarding contracts with pharmacy benefit managers concerning FROVA®. Lead plaintiffs sought class certification, damages in an unspecified amount and attorneys' fees and costs. We filed a motion to dismiss the third amended complaint in December 2016. In January 2018, the court granted our motion and dismissed the case with prejudice. In February 2018, lead plaintiffs filed a motion for relief from the judgment and leave to file a fourth amended complaint; the court denied this motion in April 2018. Lead plaintiffs appealed to the U.S. Court of Appeals for the Second Circuit; that appeal is still pending.

In February 2017, a putative class action entitled *Public Employees' Retirement System of Mississippi v. Endo International plc* was filed in the Court of Common Pleas of Chester County, Pennsylvania by an institutional purchaser of shares in our June 2, 2015 public offering, on behalf of itself and all similarly situated purchasers. The lawsuit alleges violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 against Endo, certain of its current and former directors and officers, and the underwriters who participated in the offering, based on certain disclosures about Endo's generics business. In March 2017, defendants removed the case to the U.S. District Court for the Eastern District of Pennsylvania. In August 2017, the court remanded the case back to the Chester County Court of Common Pleas. In October 2017, plaintiff filed an amended complaint. In December 2017, defendants filed preliminary objections to the amended complaint. The court denied those preliminary objections in April 2018. Plaintiff filed its motion for class certification in July 2018. In April 2019, the parties informed the court that they had reached a settlement in principle. The settlement in principle would provide the investor class $50 million in exchange for a release of their claims; the settlement is subject to court approval. As a result, the Company recorded an increase of approximately $50 million to its legal reserves as of December 31, 2018. As the Company's insurers have agreed to fund the foregoing settlement, the Company has recorded a corresponding insurance receivable of approximately $50 million to Prepaids and other current assets on its Consolidated Balance Sheet as of December 31, 2018.

In April 2017, a putative class action entitled *Phaedra A. Makris v. Endo International plc, Rajiv Kanishka Liyanaarchchie de Silva and Suketu P. Upadhyay* was filed in the Superior Court of Justice in Ontario, Canada by an individual shareholder on behalf of herself and similarly-situated Canadian-based investors who purchased Endo's securities between January 11 and May 5, 2016. The statement of claim generally seeks class certification, declaratory relief, damages, interest and costs based on alleged violations of the Ontario Securities Act. The statement of claim alleges negligent misrepresentations concerning the Group's turnover, profit margins and earnings per share; its receipt of a subpoena from the state of Connecticut regarding doxycycline hyclate, amitriptyline hydrochloride, doxazosin mesylate, methotrexate sodium and oxybutynin chloride; and the erosion of the Group's U.S. generic pharmaceuticals business. In January 2019, plaintiff amended her statement of claim to add a claim on behalf of herself and similarly-situated Canadian investors who purchased Endo's securities between January 11, 2016 and June 8, 2017. This new claim is based on the Group's decision to remove reformulated OPANA® ER from the market.

In August 2017, a putative class action entitled *Bier v. Endo International plc, et al.* was filed in the U.S. District Court for the Eastern District of Pennsylvania by an individual shareholder on behalf of himself and all similarly situated shareholders. The original complaint alleged violations of Section 10(b) and 20(a) of the Exchange Act against Endo and four current and former directors and officers, based on the Group's decision to remove reformulated OPANA® ER from the market. In December 2017, the court appointed SEB Investment Management AB lead plaintiff in the action. In February 2018, the lead plaintiff filed an amended complaint, which added claims alleging violations of Sections 11 and 15 of the Securities Act in connection with the June 2015 offering. The amended complaint named the Group, EHSI and 20 current and former directors, officers and employees of Endo as defendants. In April 2018, the defendants moved to dismiss the amended complaint. In December 2018, the court dismissed the plaintiff's claims against four individual defendants, but otherwise denied the motion to dismiss. The case is currently in discovery.

In November 2017, a putative class action entitled *Pelletier v. Endo International plc, Rajiv Kanishka Liyanaarchchie De Silva, Suketu P. Upadhyay and Paul V. Campanelli* was filed in the U.S. District Court for the Eastern District of Pennsylvania by an individual shareholder on behalf of himself and all similarly situated shareholders. The lawsuit alleges violations of Section 10(b) and 20(a) of the Exchange Act relating to the pricing of various generic pharmaceutical products. In June 2018, the court appointed *Park Employees' Annuity and Benefit Fund of Chicago* lead plaintiff in the action. In August 2018, the lead plaintiff filed an amended complaint. In September 2018, the defendants moved to dismiss the amended complaint. That motion remains pending.

We will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any additional losses that could be incurred.

VASOSTRICT® Related Matters

In July 2016, Fresenius Kabi USA, LLC (Fresenius) filed a complaint against Par Pharmaceutical Companies, Inc. and its affiliate Par Sterile Products, LLC (PSP) in the U.S. District Court for the District of New Jersey alleging that Par Pharmaceutical Companies, Inc. and its affiliate engaged in an anticompetitive scheme to exclude competition from the market for vasopressin solution for intravenous injection in view of Par Pharmaceutical Companies, Inc.'s VASOSTRICT® (vasopressin) product. The complaint alleges violations of Sections 1 and 2 of the Sherman Antitrust Act, as well as state antitrust and common law, based on assertions that Par Pharmaceutical Companies, Inc. and its affiliate entered into exclusive supply agreements with one or more active pharmaceutical ingredient (API) manufacturers and that, as a result, Fresenius has been unable to obtain vasopressin API in order to file an Abbreviated New Drug Application (ANDA) to obtain FDA approval for its own vasopressin product. Fresenius seeks actual, treble and punitive damages, attorneys' fees and costs and injunctive relief. In September 2016, Par Pharmaceutical Companies, Inc. and its affiliate filed a motion to dismiss, which the district court denied in February 2017. The case is currently in discovery.

In August 2017, our subsidiaries PPI and PSP filed a complaint for actual, exemplary and punitive damages, injunctive relief and other relief against QuVa Pharma, Inc. (QuVa), Stuart Hinchen, Peter Jenkins and Mike Rutkowski in the U.S. District Court for the District of New Jersey. The complaint alleges misappropriation in violation of the federal Defend Trade Secrets Act, New Jersey's Trade Secrets Act and New Jersey common law, as well as unfair competition, breach of contract, breach of fiduciary duty, breach of the duty of loyalty, tortious interference with contractual relations and breach of the duty of confidence in connection with VASOSTRICT®, a vasopressin-based cardiopulmonary drug. In November 2017, we filed a motion for preliminary injunction seeking various forms of relief. In January 2018, we filed a first amended complaint adding four former employees and one former consultant of PSP as defendants and numerous causes of action against some or all of those individuals, including misappropriation under the federal Defend Trade Secrets Act, New Jersey's Trade Secrets Act and New Jersey common law, as well as breach of contract, breach of the duty of loyalty and breach of the duty of confidence. In March 2018, the court granted in part our motion for preliminary injunction and enjoined QuVa from marketing and releasing its planned vasopressin product through the conclusion of trial. We subsequently deposited a bond to the court's interest-bearing account to secure the preliminary injunction. Defendants filed a motion asking the court to reconsider the bond amount, which the court denied. Also in March 2018, QuVa and seven of the individual defendants filed a motion to dismiss the New Jersey common law claims, four of the individual defendants filed a motion to dismiss for lack of personal jurisdiction and one of the individuals filed a motion to dismiss the breach of contract claim. In April 2018, another individual defendant filed a motion to dismiss asserting numerous arguments, including lack of personal jurisdiction, improper venue and choice of law. Discovery began in May 2018. Also in May 2018, defendants filed a notice of appeal to the Third Circuit Court of Appeal indicating intent to appeal the court's preliminary injunction. The parties completed appellate briefing in January 2019. Also in January 2019, the court denied all four of defendants' pending motions to dismiss. In February 2019, the defendants filed their answers and affirmative defenses, and certain defendants also filed counterclaims for defamation, tortious interference with contract, tortious interference with prospective business relations, and witness interference. The counterclaims seek actual, exemplary and punitive damages and other relief. In March 2019, we filed a motion to dismiss all of the defendants' counterclaims. This motion is still pending. In April 2019, the Third Circuit Court of Appeals affirmed the court's preliminary injunction but remanded for additional fact-finding concerning the duration of the preliminary injunction and, if needed, consideration of the additional trade secrets raised in our motion for preliminary injunction but not addressed by the preliminary injunction order.

In October 2017, Endo Par Innovation Company, LLC (EPIC) and PSP filed a complaint in the U.S. District Court for the District of Columbia challenging the legality of the FDA's *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (January 2017) with respect to the listing of vasopressin in Category 1 of the *Interim Policy*. The complaint contends that the *Interim Policy* is unlawful because it is inconsistent with the Federal Food, Drug, and Cosmetic Act, including, but not limited to, Section 503B of that Act. The complaint seeks (i) a declaration that FDA's *Interim Policy* and its listing of vasopressin in Category 1 of the *Interim Policy* are unlawful, and (ii) an order enjoining and vacating the *Interim Policy* and the FDA's listing of vasopressin in Category 1 of the *Interim Policy*. In January 2018, EPIC and PSP agreed to a temporary 60-day stay of the litigation in light of the FDA's announcement that forthcoming guidance would address the concerns set forth in the Group's complaint. In March 2018, the FDA released new draft guidance for industry entitled "Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Shortly thereafter, the parties agreed to extend the temporary stay for an additional 180 days. In August 2018, before the 180-day stay period expired, Athenex Pharma Solutions, LLC and Athenex Pharmaceutical Division, LLC announced they had commenced bulk compounding of vasopressin, and moved to intervene in EPIC and PSP's case against the FDA. Later that month, EPIC and PSP invoked their ability to terminate the stay and filed a Motion for Preliminary Injunction. Before responding to the Motion for Preliminary Injunction, the FDA issued a notice containing a proposed finding that there is no clinical need to bulk compound vasopressin under Section 503B in August 2018. In September 2018, the FDA advised EPIC and PSP that it would agree to use its best efforts to finalize the vasopressin clinical need rulemaking by December 31, 2018, if the case were again stayed. EPIC and PSP agreed to the requested stay. In December 2018, the appropriations act that had been funding the DOJ and components of the FDA expired, resulting in a lapse of appropriations; therefore, the FDA moved the court for a further stay of the case until appropriations were restored. The court granted the motion in January 2019, ordering the FDA to file a notification with the court within three business days of DOJ operations resuming. After government appropriations were restored, the FDA advised that it would use its best efforts to finalize the vasopressin clinical need determination by March 15, 2019. The FDA finalized the vasopressin clinical need determination on March 4, 2019, finding that because of VASOSTRICT®'s availability there is no clinical need for outsourcing facilities to compound drugs using bulk vasopressin. That same day, Athenex, Inc., Athenex Pharma Solutions, LLC, and Athenex Pharmaceutical Division, LLC filed a complaint in the U.S. District Court for the District of Columbia, challenging the FDA's clinical need determination for vasopressin. EPIC and PSP intervened as defendants in the action. The parties and the court agreed to an expedited summary judgment briefing, and a hearing on cross-motions for summary judgment will be held on April 30, 2019. EPIC and PSP expect a ruling by early summer. EPIC and PSP's suit against the FDA remains stayed until that ruling issues.

In August 2018, Athenex filed a declaratory judgment action in the U.S. District Court for the Western District of New York, a case styled *Athenex v. Par*, alleging non-infringement and/or invalidity of the patents the Group has listed in the Orange Book in view of VASOSTRICT®. The Group moved to dismiss Athenex's case on multiple grounds in October 2018, which motion was opposed by Athenex in December 2018. The Group responded to this opposition in December 2018. This motion has not yet been decided.

In April 2018, PSP and PPI received a notice letter from Eagle Pharmaceuticals, Inc. (Eagle) advising of the filing by such company of an ANDA for a generic version of VASOSTRICT® (vasopressin IV solution (infusion)) 20 units/ml. In May 2018, PSP and PPI received a second notice letter from Eagle advising of the same filing, but adding an additional patent. The Paragraph IV notices refer to U.S. Patent Nos. 9,375,478; 9,687,526; 9,744,209; 9,744,239; 9,750,785; and 9,937,223, which variously cover either vasopressin-containing pharmaceutical compositions or methods of using a vasopressin-containing dosage form to increase blood pressure in humans. In May 2018, PPI, PSP and EPIC filed a lawsuit against Eagle in the U.S. District Court for the District of Delaware within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. In August 2018, Eagle filed an answer and a counterclaim for non-infringement and invalidity of asserted patents. A claim construction hearing is scheduled for May 2019, with a bench trial scheduled for May 2020.

In September 2018, PSP and PPI received a notice letter from Sandoz Inc. (Sandoz) advising of the filing by such company of an ANDA for a generic version of VASOSTRICT® (vasopressin IV solution (infusion)) 200 units/10 ml. In October 2018, PPI, PSP and EPIC filed a lawsuit against Sandoz in the U.S. District Court for the District of New Jersey within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. In October 2018, PSP and PPI received an additional notice letter from Sandoz advising of the filing by such company of an ANDA for a generic version of the 20 units/1 ml presentation for VASOSTRICT®. In November 2018, the complaint was amended to add a claim for the additional notice letter, within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. The Group continues to vigorously defend its intellectual property.

In November 2018, PSP and PPI received a notice letter from Amphastar Pharmaceuticals, Inc. (Amphastar) advising of the filing by such company of an ANDA for a generic version of VASOSTRICT® (vasopressin IV solution (infusion)) 20 units/1 ml. In December 2018, PPI, PSP and EPIC filed a lawsuit against Amphastar in the U.S. District Court for the District of Delaware within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. The Group continues to vigorously defend its intellectual property.

In March 2019, PSP and PPI received a notice letter from Amneal Pharmaceuticals LLC (Amneal) advising of the filing by such company of an ANDA for a generic version of VASOSTRICT® (vasopressin IV solution (infusion)) 20 units/1 ml and 200 units/10 ml. In April 2019, PPI, PSP and EPIC filed a lawsuit against Amneal in the U.S. District Court for the District of Delaware within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. The Company continues to vigorously defend its intellectual property.

The Group's legal reserves include, among other things, an estimated accrual for certain VASOSTRICT®-related matters. We will continue to vigorously defend or prosecute the foregoing matters as appropriate, to protect our intellectual property rights, to pursue all available legal and regulatory avenues and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any additional losses that could be incurred.

Paragraph IV Certifications on OPANA® ER

In August 2014 and October 2014, the U.S. Patent Office issued U.S. Patent Nos. 8,808,737 (the '737 patent) and 8,871,779 (the '779 patent) respectively, which cover a method of using OPANA® ER and a highly pure version of the API of OPANA® ER. In November 2014, EPI filed lawsuits against Teva, ThoRx, Actavis, Impax, Ranbaxy, Roxane, Amneal and Sandoz Inc. based on their ANDAs filed against both the INTAC® technology and non-INTAC® technology versions of OPANA® ER. Those lawsuits were filed in the U.S. District Court for the District of Delaware alleging infringement of these new patents, which expire in 2027 and 2029, respectively. On November 17, 2015, the District Court held the '737 patent invalid for claiming unpatentable subject matter. That patent has been dismissed from all suits and the suits administratively closed as to that patent, subject to appeal at the end of the case on the '779 patent. In July 2016, a three-day trial was held in the U.S. District Court for the District of Delaware against Teva and Amneal for infringement of the '779 patent. In October 2016, the District Court issued an opinion holding that the defendants infringed the claims of U.S. Patent No. 8,871,779. The opinion also held that the defendants had failed to show that the '779 patent was invalid. The District Court issued an order enjoining the defendants from launching their generic products until the expiration of the '779 patent in November 2029. A trial for infringement of the '779 patent by Actavis was held in February 2017 in the same court (U.S. District Court for the District of Delaware) in front of the same judge. In August 2017, the District Court issued an opinion holding that Actavis infringed the claims of the '779 patent and that Actavis had failed to show that the '779 patent was invalid. Teva, Amneal and Actavis have appealed these holdings. We have appealed the holding that the '737 patent is invalid. A hearing on those appeals took place in December 2018.We are awaiting decisions on those appeals.

We will continue to vigorously defend or prosecute the foregoing matter as appropriate, to protect our intellectual property rights, to pursue all available legal and regulatory avenues and to explore other options as appropriate in our best interests in defense of our intellectual property, including enforcement of the product's intellectual property rights and approved labeling. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred.

Other Proceedings and Investigations

Proceedings similar to those described above may also be brought in the future. Additionally, we are involved in, or have been involved in, arbitrations or various other proceedings that arise from the normal course of our business. We cannot predict the timing or outcome of these other proceedings. Currently, neither we nor our subsidiaries are involved in any other proceedings that we expect to have a material effect on our business, financial condition, results of operations and cash flows.

Leases

We lease certain fixed assets under capital leases that expire through 2032. We lease automobiles, machinery and equipment and facilities under certain noncancelable operating leases that expire through 2028. These leases are renewable at our option.

On October 28, 2011, our subsidiary EPI entered into a lease agreement for a new Group headquarters in Malvern, Pennsylvania. The initial term of the lease is through 2024 and includes three renewal options, each for an additional 60-month period. This lease is accounted for as a direct financing arrangement whereby the Group recorded, over the construction period, the full cost of the asset in Tangible fixed assets, net. A corresponding liability was also recorded, net of leasehold improvements paid for by the Group, and is being amortized over the expected lease term through monthly rental payments using an effective interest method. At December 31, 2018, there was a liability of $33.8 million related to this arrangement, $4.9 million of which is included in Accounts payable and accrued expenses and $28.9 million of which is included in Other liabilities in the accompanying Consolidated Balance Sheet.

A summary of minimum future rental payments required under capital and operating leases as of December 31, 2018 are as follows (in thousands):

	Capital Leases (1)(2)	Operating Leases
2019	$ 6,884	$ 15,800
2020	6,819	14,519
2021	6,921	12,883
2022	7,072	12,454
2023	7,225	9,945
Thereafter	9,127	20,573
Total minimum lease payments	$ 44,048	$ 86,174
Less: Amount representing interest	4,084	
Total present value of minimum payments	$ 39,964	
Less: Current portion of such obligations	5,845	
Long-term capital lease obligations	$ 34,119	

(1) The direct financing arrangement is included under Capital Leases.

(2) We have entered into agreements to sublease certain properties. Most significantly, we sublease approximately 140,000 square feet of our Malvern, Pennsylvania headquarters and substantially all of our Chesterbrook, Pennsylvania facility. As of December 31, 2018, we expect to receive approximately $29.7 million in future minimum rental payments over the remaining terms of the Malvern and Chesterbrook subleases through 2024. Amounts included in this table have not been reduced by the minimum sublease rentals.

Expenses incurred under operating leases were approximately $18.7 million and $18.7 million for the years ended December 31, 2018 and 2017, respectively.

Contractual Obligations. The following table lists our enforceable and legally binding noncancelable obligations as of December 31, 2018.

	Payment Due by Period (in thousands)						
	Total	2019	2020	2021	2022	2023	Thereafter
Long-term debt obligations (1)	$ 8,348,775	$ 34,150	$ 34,150	$ 34,150	$ 1,134,150	$ 2,419,150	$ 4,693,025
Interest expense (2)	2,774,109	543,359	544,821	541,653	500,520	441,581	202,175
Capital lease obligations (3)	44,048	6,884	6,819	6,921	7,072	7,225	9,127
Operating lease obligations (4)	86,174	15,800	14,519	12,883	12,454	9,945	20,573
Purchase obligations (5)	69,641	27,483	16,068	12,731	1,937	1,719	9,703
Mesh-related product liability settlements (6)	258,051	258,051	—	—	—	—	—
Other obligations and commitments (7)	5,833	2,833	500	500	500	500	1,000
Total (8)	$ 11,586,631	$ 888,560	$ 616,877	$ 608,838	$ 1,656,633	$ 2,880,120	$ 4,935,603

(1) Includes minimum cash payments related to principal associated with our indebtedness as of December 31, 2018. The amounts in this table do not reflect any potential early or accelerated principal payments such as the potential payments described in Note 12. Debt.

(2) These amounts represent future cash interest payments related to our indebtedness as of December 31, 2018 based on interest rates specified in the associated debt agreements. Payments related to variable-rate debt are based on applicable market rates, estimated at December 31, 2018, plus the specified margin in the associated debt agreements for each period presented.

(3) Includes minimum cash payments related to certain fixed assets, primarily related to technology. In addition, includes minimum cash payments related to the direct financing arrangement for our U.S. headquarters in Malvern, Pennsylvania. We have entered into agreements to sublease certain properties. Most significantly, we sublease approximately 140,000 square feet of our Malvern, Pennsylvania headquarters and substantially all of our Chesterbrook, Pennsylvania facility. As of December 31, 2018, we expect to receive approximately $29.7 million in future minimum rental payments over the remaining terms of the Malvern and Chesterbrook subleases from 2019 until 2024. Amounts included in this table have not been reduced by the minimum sublease rentals.

(4) Includes minimum cash payments related to our leased automobiles, machinery and equipment, facilities and other property not included in capital lease obligations. Any proceeds for sublease income are excluded from the table above.

(5) Purchase obligations are enforceable and legally binding obligations for purchases of goods and services, including minimum stock contracts.

(6) The amounts included above represent contractual payments for mesh-related product liability settlements and reflect the earliest date that a settlement payment could be due and the largest amount that could be due on that date. These matters are described in more detail in Note 13. Commitments and Contingencies.

(7) Other obligations and commitments include agreements to purchase third-party assets, products and services and other minimum royalty obligations.

(8) Total generally does not include contractual obligations already included in current liabilities on our Consolidated Balance Sheets, except for current portion of long-term debt, accrued interest, short-term capital lease obligations, mesh-related product liabilities and certain purchase obligations, which are discussed below.

For purposes of the table above, obligations for the purchase of goods or services are included only for significant noncancelable purchase orders at least one year in length that are enforceable, legally binding and specify all significant terms, including fixed or minimum quantities to be purchased, fixed, minimum or variable price provisions and the timing of the obligation. In cases where our minimum obligations are variable based on future contingent events or circumstances, we estimate the minimum obligations based on information available to us at the time of disclosure. Our purchase orders are based on our current manufacturing needs and are typically fulfilled by our suppliers within a relatively short period. At December 31, 2018, we have open purchase orders that represent authorizations to purchase, rather than binding agreements, that are not included in the table above. In addition, we do not include collaboration agreements and potential payments under those agreements or potential payments related to contingent consideration.

Information about our liability for unrecognized tax benefits is included in Note 18. Income Taxes under the caption "Uncertain Tax Positions." Due to the nature and timing of the ultimate outcome of these uncertain tax positions, we cannot make a reliable estimate of the amount and period of related future payments. Therefore, our liability has been excluded from the above contractual obligations table.

NOTE 14. OTHER COMPREHENSIVE PROFIT (LOSS)

Set forth below are the tax effects allocated to each component of Other comprehensive (loss) profit for the years ended December 31, 2018 and 2017 (in thousands):

	2018			2017		
	Before-Tax Amount	Tax (Expense) Benefit	Net-of-Tax Amount	Before-Tax Amount	Tax Benefit (Expense)	Net-of-Tax Amount
Net unrealized loss on securities:						
Unrealized loss arising during the period	$ —	$ —	$ —	$ (811)	$ 296	$ (515)
Less: reclassification adjustments for (profit) loss realized in net loss	—	—	—	—	—	—
Net unrealized profits (losses) on securities	$ —	$ —	$ —	$ (811)	$ 296	$ (515)
Net unrealized (loss) profit on foreign currency:						
Foreign currency translation (loss) profit arising during the period	(19,408)	—	(19,408)	31,202	—	31,202
Less: reclassification adjustments for loss realized in net loss	—	—	—	112,926	—	112,926
Foreign currency translation (loss) profit	$ (19,408)	$ —	$ (19,408)	$ 144,128	$ —	$ 144,128
Other comprehensive (loss) profit	$ (19,408)	$ —	$ (19,408)	$ 143,317	$ 296	$ 143,613

Reclassification adjustments out of Other comprehensive (loss) profit related to foreign currency translation were recorded upon the liquidation of Litha and Somar during 2017.

Substantially all of the Group's Accumulated other comprehensive loss at December 31, 2018 and December 31, 2017 consists of Foreign currency translation loss.

NOTE 15. SHARE CAPITAL

On February 11, 2014, the Group issued 4,000,000 euro deferred shares of $0.01 each at par. The euro deferred shares are held by nominees in order to satisfy an Irish legislative requirement to maintain a minimum level of issued share capital denominated in euro and to have at least seven registered shareholders. The euro deferred shares carry no voting rights and are not entitled to receive any dividend or distribution.

Share Capital consists of the following for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Authorized:		
4,000,000 Euro deferred shares of $0.01 par value	$ 40	$ 40
1,000,000,000 ordinary shares of $0.0001 par value	100	100
Total share capital	$ 140	$ 140
Allotted, called-up and fully paid equity:		
BALANCE, DECEMBER 31, 2017		$ 64
Other		6
BALANCE, DECEMBER 31, 2017		$ 70
Other		(2)
BALANCE, DECEMBER 31, 2018		$ 68

Share Repurchase Program

The Group has broad shareholder authority pursuant to Article 11 of the Group's Articles of Association to conduct repurchase by way of redemptions of its ordinary shares.

Pursuant to the 2014 Share Buyback Authority, in April 2015, our Board of Directors approved a share buyback program (the 2015 Share Buyback Program). The 2015 Share Buyback Program authorized the Group to redeem in the aggregate $2.5 billion of its outstanding ordinary shares. As permitted by Irish Law and the Group's Articles of Association, all ordinary shares redeemed under the 2015 Share Buyback Program shall be cancelled upon redemption.

NOTE 16. SHARE-BASED COMPENSATION

As discussed in Note 3. Discontinued Operations and Divestitures, the operating results of the Group's Astora businesses are reported as Discontinued operations, net of tax in the Consolidated Profit and Loss Account for all periods presented. However, as share-based compensation is not material for these businesses, amounts in this Note 16. Share-Based Compensation have not been adjusted to exclude the impact of these businesses.

Stock Incentive Plans

In June 2015, the Group's shareholders approved the 2015 Stock Incentive Plan (the 2015 Plan), which has subsequently been amended, as approved by the Group's shareholders, on multiple occasions, including in 2017 and 2018. Under the 2015 Plan, stock options (including incentive stock options), stock appreciation rights, restricted stock awards, performance awards and other share- or cash-based awards may be issued at the discretion of the Board of Directors from time to time. No ordinary shares are to be granted under previously approved plans, including the Group's 2000, 2004, 2007, 2010 and Assumed Stock Incentive Plans. All awards previously granted and outstanding under these prior plans remain subject to the terms of those prior plans.

During the third quarter of 2017, the Group issued approximately 1.0 million stock options and 0.1 million restricted stock units that were initially subject to shareholder approval and were subsequently approved by shareholders on June 7, 2018 at the Group's Annual General Meeting of Shareholders. The options have an exercise price equal to the closing share price on their issuance date in August 2017. For accounting and disclosure purposes, these stock options and restricted stock units were considered to have been granted in 2018 upon approval by shareholders.

As further described below, certain of the Group's outstanding Performance Share Units (PSUs) are measured upon the completion of three independent successive one-year performance targets, which are generally established for each performance period during the first quarter of that calendar year. The determination of the grant-date(s) underlying such PSUs depends in part on the date(s) on which each of the performance targets with respect to those PSUs are approved. Therefore, for certain PSUs, a single unit may give rise to multiple grant dates depending, in part, on the dates on which the respective performance targets are approved. As of December 31, 2018, there are 0.5 million PSUs outstanding, representing target amounts, for which a grant date has not yet been established. No fair value has been ascribed to these awards as no grant date has been established.

Beginning in 2017, long-term cash incentive (LTCI) awards were provided to certain employees. LTCI awards were designed to vest ratably, in equal amounts, over a three-year service period. Upon vesting, each vested LTCI unit would be settled in cash in an amount equal to the price of Endo's ordinary shares on the vest date. As of September 30, 2018, approximately 3.0 million unvested LTCI awards were outstanding for approximately 570 employees. The outstanding awards had a weighted average remaining requisite service period of 2.3 years. A corresponding liability of $14.9 million was recorded as of September 30, 2018 in Accounts payable and accrued expenses and Other liabilities in the Group's Condensed Consolidated Balance Sheets. On October 1, 2018, the Compensation Committee of the Board of Directors authorized the Group to settle each of the outstanding unvested LTCI awards in shares, rather than cash, upon vesting in accordance with the original vesting terms of the awards. With the authorization of the Compensation Committee, management's intent to settle the awards in shares rather than cash is a modification that changes the awards' classification from liability to equity, effective October 1, 2018. The accounting for the modification occurred in the fourth quarter of 2018. Prior to this modification, LTCI awards were excluded from amounts in this Note 16. Share-Based Compensation. Subsequent to this modification, LTCI awards are generally treated the same as restricted stock units (RSUs), including for accounting, financial statement classification and disclosure purposes. However, adjustments to pre-modification amounts of LTCI expense that are recorded in the Consolidated Profit and Loss Account subsequent to this modification, including adjustments related to actual or estimated forfeitures, are excluded from the determination of share-based compensation expense.

At December 31, 2018, approximately 5.5 million ordinary shares were reserved for future grants under the 2015 Plan. As of December 31, 2018, stock options, restricted stock awards, PSUs, RSUs and LTCI awards have been granted under the stock incentive plans.

Generally, the grant-date fair value of each award is recognized as expense over the requisite service period. However, expense recognition differs in the case of certain performance share units where the ultimate payout is performance-based. For these awards, at each reporting period, the Group estimates the ultimate payout and adjusts the cumulative expense based on its estimate and the percent of the requisite service period that has elapsed.

Presented below are the components of total share-based compensation as recorded in our Consolidated Profit and Loss Account for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Selling, general and administrative expenses	$ 44,454	$ 38,292
Research and development expenses	2,251	4,197
Cost of sales	7,366	7,660
Total share-based compensation expense	$ 54,071	$ 50,149

As of December 31, 2018, the total remaining unrecognized compensation cost related to all non-vested share-based compensation awards for which a grant date has been established as of December 31, 2018 amounted to $68.3 million.

Stock Options

From time to time, the Group grants stock options to its employees as part of their annual share compensation awards and, in certain circumstances, on an ad hoc basis or upon their commencement of service with the Group.

Employee stock options generally vest ratably, in equal amounts, over a three or four-year service period and expire ten years from the grant date. The fair value of option grants is estimated at the date of grant using the Black-Scholes option-pricing model. This model utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero as the Group has not paid cash dividends to date and does not currently expect to pay cash dividends) and the expected term of the option. Expected volatilities utilized in the model are based mainly on the historical volatility of the Group's share price over a period commensurate with the expected life of the share option as well as other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. We estimate the expected term of options granted based on our historical experience with our employees' exercise of stock options and other factors.

A summary of the activity for each of the years ended December 31, 2018 and 2017 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (1)
Outstanding as of January 1, 2017	4,325,209	$ 41.70		
Granted	5,288,675	$ 10.42		
Forfeited	(623,987)	$ 28.32		
Expired	(741,767)	$ 40.29		
Outstanding as of December 31, 2017	8,248,130	$ 22.79		
Granted	971,590	$ 7.55		
Exercised	(94,392)	$ 9.89		
Forfeited	(605,737)	$ 19.01		
Expired	(446,873)	$ 36.80		
Outstanding as of December 31, 2018	8,072,718	$ 20.62	7.12	$ —
Vested and expected to vest as of December 31, 2018	7,833,930	$ 20.86	7.08	$ —
Exercisable as of December 31, 2018	3,550,777	$ 28.07	6.00	$ —

(1) The intrinsic value of a stock option is the excess, if any, of the closing price of the Group's ordinary shares on the last trading day of the fiscal year over the exercise price. The aggregate intrinsic values presented in the table above represent sum of the intrinsic values of all corresponding stock options that are "in-the-money," if any.

The range of exercise prices for the above stock options outstanding at December 31, 2018 is from $7.55 to $89.68.

No options were exercised during the year ended December 31, 2017. The total intrinsic value of options exercised during the year ended December 31, 2018 was $0.6 million. No tax benefits from stock option exercises were realized during the years ended December 31, 2018 and 2017. The weighted average grant-date fair value of the stock options granted in the years ended December 31, 2018 and 2017 was $3.97 and $4.73, respectively, determined using the following average assumptions:

	2018	2017
Expected term (years)	4.0	4.0
Risk-free interest rate	2.7%	1.7%
Dividend yield	—	—
Expected volatility	63%	58%

As of December 31, 2018, the weighted average remaining requisite service period of non-vested stock options was 1.7 years and the total remaining unrecognized compensation cost related to non-vested stock options amounted to $9.4 million.

Restricted Stock Units and Performance Share Units

For PSUs for which a grant date has not yet occurred, such as those described above, no fair value has been established and these awards are not reflected in any of the amounts in this "Restricted Stock Units and Performance Share Units" section.

From time to time, the Group grants RSUs and PSUs to its employees as part of their annual share compensation awards and, in certain circumstances, on an ad hoc basis or upon their commencement of service with the Group.

RSUs vest ratably, in equal amounts, over a three or four-year service period. PSUs vest in full after a three-year service period and are conditional upon the achievement of performance and/or market conditions established by the Compensation Committee of the Board of Directors.

PSUs awarded in 2018 and 2017 were based upon two discrete measures: relative total shareholder return (TSR) and a free cash flow performance metric. The free cash flow performance metric, which accounts for 50% of the PSU award upon issuance, is measured upon the completion of three independent successive one-year performance targets, which are generally established for each performance period during the first quarter of that calendar year. The remaining 50% of the PSU award is tied exclusively to relative TSR performance, which will be measured against the three-year TSR of a custom index of companies. The actual number of shares awarded is adjusted to between zero and 200% of the target award amount based upon achievement of certain goals. In addition to meeting the performance conditions, grant recipients are also generally subject to being employed by the Group until the conclusion of the three-year vesting period in order to receive the awards. TSR relative to peers is considered a market condition under applicable authoritative guidance, while the free cash flow measure is considered performance condition.

In 2016, PSU grants are tied to relative TSR performance, which will be measured against the three-year TSR of a custom index of companies, with maximum payout levels also based on absolute compounded annual growth rate (CAGR) share price objectives. Each award covered a three-year performance cycle. The actual number of shares awarded is adjusted to between zero and 300% of the target award amount based upon achievement of pre-determined relative TSR and CAGR share price goals. TSR relative to peers is considered a market condition under applicable authoritative guidance.

RSUs are valued based on the closing price of Endo's ordinary shares on the date of grant. PSUs with TSR conditions are valued using a Monte-Carlo variant valuation model, while those with adjusted free cash flow conditions are valued taking into consideration the probability of achieving the specified performance goal. The Monte-Carlo variant valuation model considered a variety of potential future share prices for Endo as well as our peer companies in a selected market index.

A summary of our non-vested RSUs and PSUs for the years ended December 31, 2018 and 2017 is presented below:

	Number of Shares	Aggregate Intrinsic Value (1)
Non-vested as of January 1, 2017	1,685,060	
Granted	4,168,477	
Forfeited	(552,981)	
Vested	(575,883)	
Non-vested as of December 31, 2017	4,724,673	
Granted	5,609,561	
LTCI modification (2)	2,989,965	
Forfeited	(753,653)	
Vested	(1,551,074)	
Non-vested as of December 31, 2018	11,019,472	$ 80,442,146
Vested and expected to vest as of December 31, 2018	10,250,560	$ 74,829,088

(1) The aggregate intrinsic values of RSUs and PSUs presented in the table above are calculated by multiplying the closing price of the Group's ordinary shares on the last trading day of the fiscal year by the corresponding number of RSUs and PSUs.

(2) As a result of the October 1, 2018 modification to the Group's LTCI awards described above, modified LTCI awards are treated as RSUs for disclosure purposes; thus, the table above reflects an increase to the non-vested number of shares on the modification date.

As of December 31, 2018, the weighted average remaining requisite service period of the units presented in the table above was 1.9 years and the corresponding total remaining unrecognized compensation cost amounted to $54.2 million in the case of RSUs and LTCI awards and $4.7 million in the case of PSUs. The weighted average grant-date fair value of the units granted during the years ended December 31, 2018 and 2017 was $6.88 and $11.42 per unit, respectively.

NOTE 17. OTHER INCOME, NET

The components of Other income, net for the years ended December 31, 2018, 2017 and 2016 are as follows (in thousands):

	2018	2017
Net (gain) loss on sale of business and other assets	$ (45,155)	$ (13,809)
Foreign currency (gain) loss, net	(3,762)	(2,801)
Net loss (gain) from our investments in the equity of other companies	3,444	898
Other miscellaneous, net	(6,480)	(1,311)
Other income, net	$ (51,953)	$ (17,023)

In 2018, Net (gain) loss on sale of business and other assets primarily relates to proceeds received from the 2018 sales of various ANDAs and of the Huntsville facilities, as further discussed in Note 4. Restructuring.

In 2017, Net (gain) loss on sale of business and other assets includes a $10.1 million gain resulting from the sale of Litha, as further described in Note 3. Discontinued Operations and Divestitures.

Amounts of Foreign currency (gain) loss, net result from the remeasurement of the Group's foreign currency denominated assets and liabilities. Net loss (gain) from our investments in the equity of other companies includes the profit and loss account impacts of our investments in the equity of other companies, including those accounted for under the equity method and those classified as marketable securities.

NOTE 18. INCOME TAXES

Tax Reform

The TCJA, which was signed into law on December 22, 2017, has resulted in significant changes to the U.S. corporate income tax system. In addition to the reduction of the U.S. statutory federal corporate income tax rate from 35% to 21% effective January 1, 2018, the TCJA contains a broad range of domestic and international provisions, many of which differ significantly from those contained in previous U.S. tax law. Although the rate of U.S. federal income tax was reduced prospectively, changes in tax rates and laws are accounted for in the period of enactment. Therefore, during the year ended December 31, 2017, we recorded a benefit of $36.2 million as our provisional estimate of the impact of the TCJA in accordance with Staff Accounting Bulletin (SAB) 118. This benefit, which is primarily related to remeasurement of deferred tax liabilities related to tax deductible goodwill, has been recorded in our Consolidated Profit and Loss Account as Income tax benefit. The Group has completed its accounting for the tax effects of the TCJA in accordance with SAB 118. There were no significant adjustments to the provisional amounts recorded.

Profit (Loss) Before Income Taxes

Our operations are conducted through our various subsidiaries in numerous jurisdictions throughout the world. We have provided for income taxes based upon the tax laws and rates in the jurisdictions in which our operations are conducted.

The components of our Loss from continuing operations before income tax by geography for the years ended December 31, 2018 and 2017 are as follows (in thousands):

	2018	2017
United States	$ (1,342,860)	$ (1,866,222)
International	404,028	383,218
Total loss from continuing operations before income tax	$ (938,832)	$ (1,483,004)

Income tax from continuing operations consists of the following for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Current:		
U.S. Federal	$ 6,236	$ (86,478)
U.S. State	2,864	(6,462)
International	8,278	(1,224)
Total current income tax	$ 17,378	$ (94,164)
Deferred:		
U.S. Federal	$ 10,084	$ (124,682)
U.S. State	(778)	(3,225)
International	(3,749)	(28,222)
Total deferred income tax	$ 5,557	$ (156,129)
Total income tax	$ 22,935	$ (250,293)

Tax Rate

A reconciliation of income tax from continuing operations at the U.S. federal statutory income tax rate to the total income tax provision from continuing operations for the years ended December 31, 2018 and 2017 is as follows (in thousands):

	2018	2017
Notional U.S. federal income tax provision at the statutory rate	$ (197,155)	$ (519,051)
State income tax, net of federal benefit	494	(11,473)
U.S. tax reform impact	5,664	(36,216)
Uncertain tax positions	46,317	58,120
Residual tax on non-U.S. net earnings	(638,724)	(1,350,811)
Non-deductible goodwill impairment	109,189	60,808
Change in valuation allowance	752,008	1,648,836
Intra-entity transfers of assets	(63,335)	(53,509)
International Pharmaceuticals segment divestitures	—	(56,092)
Other	8,477	9,095
Income tax	$ 22,935	$ (250,293)

During the year ended December 31, 2018, the tax expense primarily related to the establishment of a valuation allowance against certain U.S. deferred tax assets. During the year ended December 31, 2017, the tax benefit primarily related to pre-tax losses incurred by certain U.S. subsidiaries.

Deferred Tax Assets and Liabilities

Deferred income taxes result from temporary differences between the amount of assets and liabilities recognized for financial reporting and tax purposes. The significant components of the net deferred income tax liability shown on the balance sheets as of December 31, 2018 and 2017 are as follows (in thousands):

	December 31, 2018	December 31, 2017
Deferred tax assets:		
Accrued expenses and customer allowances	$ 185,910	$ 299,142
Deferred interest expense	240,736	46,230
Fixed assets and intangible assets	604,385	484,313
Loss on capital assets	62,033	49,585
Net operating loss carryforward	8,751,544	7,183,651
Other	65,266	56,828
Research and development and other tax credit carryforwards	9,551	6,354
Total gross deferred income tax assets	$ 9,919,425	$ 8,126,103
Deferred tax liabilities:		
Other	$ (1,965)	$ (2,042)
Outside basis difference	(73,652)	(92,635)
Total gross deferred income tax liabilities	$ (75,617)	$ (94,677)
Valuation allowance	(9,877,617)	(8,062,975)
Net deferred income tax liability	$ (33,809)	$ (31,549)

At December 31, 2018, the Group had the following significant deferred tax assets for net operating and capital loss carryforwards, net of unrecognized tax benefits (in thousands):

Jurisdiction		Amount	Begin to Expire
Ireland	$	13,254	indefinite
Luxembourg	$	8,378,742	2034
United States:			
Federal-ordinary losses	$	176,695	2020
Federal-capital losses	$	35,673	2022
State-ordinary losses	$	178,732	2019
State-capital losses	$	25,524	2026

A valuation allowance is required when it is more likely than not that all or a portion of a deferred tax asset will not be realized. The Group assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable profit during the carryforward period are reduced or increased, or if objective negative evidence, in the form of cumulative losses, is no longer present and additional weight may be given to subjective evidence, such as projections for growth.

The Group has recorded a valuation allowance against certain jurisdictional net operating loss carryforwards and other tax attributes. As of December 31, 2018 and 2017, the total valuation allowance was $9,877.6 million and $8,063.0 million, respectively. During the years ended December 31, 2018 and 2017, the Group increased its valuation allowance in the amount of $1,814.6 million and $3,221.8 million, respectively.

The net increase in the Group's valuation allowance in 2018 was primarily driven by losses within jurisdictions unable to support recognition of a deferred tax asset, of which the largest jurisdiction was Luxembourg, where the Group had significant interest expense and losses on its investments in the equity of consolidated subsidiaries.

The net increase in the Group's valuation allowance in 2017 was primarily driven by: (i) $3,310.8 million related to losses within jurisdictions unable to support recognition of a deferred tax asset, of which the largest jurisdiction was Luxembourg, where the Group recognized a significant loss on its investment in the equity of consolidated subsidiaries, (ii) the establishment of a $479.7 million valuation allowance offsetting net deferred tax assets that was created in connection with the January 1, 2017 adoption of ASU No. 2016-16, "*Intra-Entity Transfers of Assets Other Than Inventory*" and that primarily relates to certain intangibles and tax deductible goodwill and (iii) $21.5 million relating to state tax benefits. This increase was partially offset by a $590.2 million reduction related to remeasurement of certain deferred tax assets resulting from the TCJA.

At December 31, 2018, the Group had the following significant valuation allowances (in thousands):

Jurisdiction		December 31, 2018
Ireland	$	160,867
Luxembourg	$	8,378,742
United States	$	1,334,463

We have provided income taxes for earnings that are currently distributed as well as the taxes associated with certain earnings that are expected to be distributed in the future. No additional provision has been made for Irish and non-Irish income taxes on the undistributed earnings of subsidiaries or for unrecognized deferred tax liabilities for temporary differences related to basis differences in investments in subsidiaries as such earnings are expected to be indefinitely reinvested, the investments in subsidiaries are essentially permanent in duration. As of December 31, 2018, certain subsidiaries had approximately $1,231.8 million of cumulative undistributed earnings that have been permanently reinvested because our plans do not demonstrate a need to repatriate such earnings. A liability could arise if our intention to indefinitely reinvest such earnings were to change and amounts are distributed by such subsidiaries or if such subsidiaries are ultimately disposed. It is not practicable to estimate the additional income taxes related to indefinitely reinvested earnings or the basis differences related to investments in subsidiaries.

Uncertain Tax Positions

The Group and its subsidiaries are subject to income taxes in the U.S., various states and numerous foreign jurisdictions with varying statutes as to which tax years are subject to examination by the tax authorities. The Group has taken positions on its tax returns that may be challenged by various tax authorities for which reserves have been established for tax-related uncertainties. The Group endeavors to resolve matters with a tax authority at the examination level and could reach agreement with a tax authority at any time. The accruals for tax-related uncertainties are based on the Group's best estimate of the potential tax exposures. When particular matters arise, a number of years may elapse before such matters are audited and finally resolved, and the final outcome with a tax authority may result in a tax liability that is more or less than that reflected in our financial statements. Favorable resolution of such matters could be recognized as a reduction of the Group's effective tax rate in the year of resolution, while a resolution that is not favorable could increase the effective tax rate and may require the use of cash in the year of resolution. Uncertain tax positions are reviewed quarterly and adjusted as necessary when events occur that affect potential tax liabilities, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, identification of new issues and issuance of new legislation, regulations or case law.

As of December 31, 2018, the Group had total unrecognized income tax benefits of $479.4 million. If recognized in future years, $304.3 million of these currently unrecognized income tax benefits would impact the income tax provision and effective tax rate. As of December 31, 2017, the Group had total unrecognized tax benefits of $435.1 million. If recognized in future years, $289.9 million of these unrecognized income tax benefits would have impacted the income tax provision and effective tax rate. The following table summarizes the activity related to unrecognized income tax benefits during the years ended December 31, 2018 and 2017 (in thousands):

	Unrecognized Tax Benefit Federal, State, and Foreign Tax
UTB Balance at January 1, 2017	$ 424,601
Gross additions for current year positions	44,293
Gross reductions for prior period positions	(64,887)
Gross additions for prior period positions	22,765
Decrease due to lapse of statute of limitations	(13,151)
Currency translation adjustment	2,330
UTB Balance at December 31, 2017	$ 415,951
Gross additions for current year positions	36,088
Gross reductions for prior period positions	(3,570)
Gross additions for prior period positions	7,950
Decrease due to lapse of statute of limitations	(2,129)
Currency translation adjustment	(2,600)
UTB Balance at December 31, 2018	$ 451,690
Accrued interest and penalties	27,739
Total UTB balance including accrued interest and penalties	$ 479,429

The Group records accrued interest as well as penalties related to uncertain tax positions as part of the provision for income taxes. As of December 31, 2018 and 2017, $27.7 million and $19.2 million, respectively, of corresponding accrued interest and penalties is included in the Consolidated Balance Sheets, all of which is recorded in income taxes.

During the years ended December 31, 2018 and 2017, we recognized expense of $8.6 million and $1.4 million, respectively, related to interest and penalties. The current portion of our UTB liability of $6.5 million is included in our Consolidated Balance Sheet as Accounts payable and accrued expenses. The non-current portion of our UTB liability is included in our Consolidated Balance Sheet as Other liabilities or, if and to the extent appropriate, as a reduction to Deferred tax assets.

Our subsidiaries file income tax returns in the countries in which they have operations. Generally, these countries have statutes of limitations ranging from 3 to 5 years. Certain subsidiary tax returns are currently under examination by taxing authorities, including U.S. tax returns for the 2011 through 2015 tax years by the Internal Revenue Service.

It is expected that the amount of unrecognized tax benefits will change during the next twelve months; however, the Group does not anticipate any adjustments that would lead to a material impact on our results of operations or our financial position.

As of December 31, 2018, we may be subject to examination in the following major tax jurisdictions:

Jurisdiction	Open Years
Canada	2013 through 2018
India	2013 through 2018
Ireland	2014 through 2018
Luxembourg	2014 through 2018
United States - federal, state and local	2006 through 2018

NOTE 19. NET LOSS PER SHARE

The following is a reconciliation of the numerator and denominator of basic and diluted net loss per share for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Numerator:		
Loss from continuing operations	$ (961,767)	$ (1,232,711)
Loss from discontinued operations, net of tax	(69,702)	(802,722)
Net loss	$ (1,031,469)	$ (2,035,433)
Denominator:		
For basic per share data—weighted average shares	223,960	223,198
Dilutive effect of ordinary share equivalents	—	—
For diluted per share data—weighted average shares	223,960	223,198

Basic net loss per share amounts are computed based on the weighted average number of ordinary shares outstanding during the period. Diluted net loss per share amounts are computed based on the weighted average number of ordinary shares outstanding and, if there is net profit from continuing operations during the period, the dilutive impact of ordinary share equivalents outstanding during the period.

The dilutive effect of ordinary share equivalents is measured using the treasury stock method. Stock options and awards that have been issued but for which a grant date has not yet been established, such as the performance share units discussed in Note 16. Share-Based Compensation, are not considered in the calculation of basic or diluted weighted average shares.

All potentially dilutive items were excluded from the diluted share calculation for the years ended December 31, 2018 and 2017 because their effect would have been anti-dilutive, as the Group was in a loss position.

NOTE 20. SAVINGS AND INVESTMENT PLAN AND DEFERRED COMPENSATION PLANS

Savings and Investment Plan

The Group maintains a defined contribution Savings and Investment Plan (the Endo 401(k) Plan) covering all U.S.-based eligible employees. The Group matches 100% of the first 3% of eligible cash compensation that a participant contributes to the Endo 401(k) Plan plus 50% of the next 2% for a total of up to 4%, subject to statutory limitations. Participants are immediately vested with respect to their own contributions and the Group's matching contributions, except that, for employees hired after 2017, the Group's matching contributions will vest ratably over a two-year period.

Costs incurred for contributions made by the Group to the Endo 401(k) Plan amounted to $6.4 million and $9.4 million for the years ended December 31, 2018 and 2017, respectively.

Directors Stock Election Plan

The Group maintains a directors stock election plan. The purpose of this plan is to provide non-employee directors the opportunity to have their cash retainer fees, or a portion thereof, delivered in the form of Endo ordinary shares. The amount of shares will be determined by dividing the portion of cash fees elected to be received as shares by the closing price of the shares on the day the payment would have otherwise been paid in cash.

NOTE 21. DEBTORS

The components of Debtors for the years ended December 31, 2018 and 2017 (in thousands) were as follows:

	2018	2017
Amounts falling due within one year:		
Trade debtors	$ 470,570	$ 517,436
Prepayments and other debtors	106,139	43,098
Income taxes receivable	39,781	12,048
	$ 616,490	$ 572,582
Amounts falling due after more than one year:		
Deferred tax asset	$ 678	$ 11,582
Other debtors	66,993	59,728
	$ 67,671	$ 71,310

NOTE 22. PROVISIONS AND CREDITORS

The components of Provisions and Creditors for the years ended December 31, 2018 and 2017 (in thousands) were as follows:

	Note	2018	2017
Provisions for liabilities:			
Amounts falling due within one year:			
Returns and allowances, rebates, chargebacks		$ 384,777	$ 473,971
Acquisition-related contingent consideration—short-term	6	36,514	70,543
		$ 421,291	$ 544,514
Amounts falling due after more than one year:			
Acquisition-related contingent consideration—long-term	6	80,189	119,899
		$ 501,480	$ 664,413
Creditors:			
Amounts falling due within one year:			
Current portion of legal settlement accrual	13	$ 955,085	$ 1,087,793
Accrued expenses		491,885	466,963
Trade accounts payable		96,024	85,348
Income taxes payable		1,661	2,086
		$ 1,544,655	$ 1,642,190
Amounts falling due after more than one year:			
Income taxes payable		$ 261,109	$ 236,273
Long-term legal settlement accrual, less current portion, net	13	—	210,450
Deferred income taxes		34,487	43,131
Other creditors		80,526	78,006
		$ 376,122	$ 567,860
		$ 1,920,777	$ 2,210,050

The following table summarizes changes in the ending balances for our product sales provisions from December 31, 2018 and 2017 (in thousands):

	Returns and Allowances	Rebates	Chargebacks	Total
Balance, December 31, 2017	$ 291,034	$ 168,333	$ 14,604	$ 473,971
Current year provision	78,558	325,690	18,182	422,430
Adjustments to prior year provision	3,694	(4,705)	1,571	560
Payments or credits	(136,340)	(345,071)	(30,773)	(512,184)
Balance, December 31, 2018	$ 236,946	$ 144,247	$ 3,584	$ 384,777

NOTE 23. CAPITAL EXPENDITURE COMMITMENTS

The directors have authorized the Group to spend $92 million for capital expenditures in the year ended December 31, 2019.

NOTE 24. RELATED PARTY DISCLOSURES

The principal related party relationships requiring disclosure in the Consolidated Financial Statements pertain to the existence of subsidiaries and associates and transactions with these entities entered into by the Group and the identification of key management personnel as addressed in greater detail below.

Subsidiaries and Associates

The Consolidated Financial Statements include the results of operations, financial positions and cash flows of the Group and its subsidiaries and associates over which the Group has control. A listing of principal subsidiaries and associates is provided in Note 28. Subsidiaries.

Trading Transactions

There were no transactions requiring disclosure under Sch. 3, Part IV, 67 of the Irish Companies Act, 2014.

Compensation of Key Management Personnel of the Group

Key management personnel are the Group’s executive and non-executive directors and their compensation is disclosed in Note 26. Directors' Remuneration.

NOTE 25. EMPLOYEES

The average number of persons employed by the Group for the years ended December 31, 2018 and 2017 were as follows:

	2018	2017
Manufacturing	1,655	2,175
Research and development	394	457
Selling, general and administrative	897	1,001
Total employees	2,946	3,633

Employee costs for the years ended December 31, 2018 and 2017 (in thousands) were as follows:

	2018	2017
Wages and salaries	$ 352,752	$ 424,099
Benefits (1)	77,607	81,120
Share-based compensation	54,071	50,149
Total employee cost	$ 484,430	$ 555,368

(1) Benefits include social security costs, employer paid payroll taxes and other employee benefits paid by the Group.

NOTE 26. DIRECTORS' REMUNERATION

Directors' remuneration set forth in the table below consists of compensation to all non-employee directors in their capacities as such, and includes cash payments made and the grant date fair value of equity awards granted. Remuneration for the years ended December 31, 2018 and 2017 were as follows (in thousands):

	2018	2017
Emoluments	$ 780	$ 1,049
Benefits under long-term incentive schemes	$ 1,440	$ 1,966
Contributions to retirement benefit schemes:		
Defined contribution	$ —	$ —
Defined benefit	—	—
	$ —	$ —
Compensation for loss of office paid by the company and other termination payments	$ —	$ —

NOTE 27. AUDITORS' REMUNERATION

PricewaterhouseCoopers LLP served as the Group's independent registered public accounting firm for the years ended December 31, 2018 and 2017. The table below summarizes the aggregate fees for services PricewaterhouseCoopers LLP provided during years 2018 and 2017, respectively.

	2018	2017
Audit fees (1)	$ 7,781	$ 9,128
Audit-related fees (2)	626	632
Tax fees (3)	3,617	1,936
All other fees (4)	237	7
Total auditors' remuneration	$ 12,261	$ 11,703

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(1) Fees for audit services in 2018 and 2017 consisted of:
- Audit of the Group's annual financial statements;
- Evaluation and reporting on the effectiveness of the Group's internal controls over financial reporting;
- Reviews of the Group's quarterly financial statements;
- Statutory audits for the Group and certain of its subsidiaries; and
- Comfort letters, consents and other services related to debt issuances and other SEC matters.

(2) Fees for audit-related services in 2018 and 2017 consisted of:
- Attestation services requested by management;
- Due diligence services; and
- Pre- or post- implementation reviews of processes or systems.

(3) Fees for tax services in 2018 and 2017 consisted of tax compliance and tax planning and advice.
- Tax compliance;
- Statutory tax return preparation and review; and
- Tax planning and advice, including advice related to the impact of changes in tax laws.

(4) All other fees in 2018 principally includes compliance advisory services and subscriptions to knowledge tools. All other fees in 2017 principally includes subscriptions to knowledge tools.

NOTE 28. SUBSIDIARIES

The subsidiaries of Endo International plc are wholly-owned by Endo International plc or one of its subsidiaries. The following is a list of the subsidiaries that principally affect the Group's statutory financial statements:

Subsidiary	Jurisdiction of Incorporation or Organization	Ownership by Endo International plc	Percent of Ownership
Actient Therapeutics, LLC	Delaware	Indirect	100%
Anchen Pharmaceuticals 2, Inc.	Delaware	Indirect	100%
Astora Women's Health, LLC	Delaware	Indirect	100%
Auxilium Pharmaceuticals, LLC	Delaware	Indirect	100%
Endo Bermuda Finance Limited	Bermuda	Indirect	100%
Endo DAC	Ireland	Direct	100%
Endo Finance II Limited	Ireland	Indirect	100%
Endo Finance IV Limited	Ireland	Indirect	100%
Endo Finance Limited	Ireland	Indirect	100%
Endo Finance LLC	Delaware	Indirect	100%
Endo Finance Operations LLC	Delaware	Indirect	100%
Endo Global Biologics Limited	Ireland	Indirect	100%
Endo Global Ventures	Bermuda	Indirect	100%
Endo Health Solutions Inc.	Delaware	Indirect	100%
Endo Ireland Finance Limited	Ireland	Indirect	100%
Endo Luxembourg Finance Company I S.a r.l.	Luxembourg	Indirect	100%
Endo Luxembourg Finance Company II S.a r.l.	Luxembourg	Indirect	100%
Endo Luxembourg Holding Company S.a r.l.	Luxembourg	Indirect	100%
Endo Management Limited	Ireland	Indirect	100%
Endo Par Innovation Company, LLC	Delaware	Indirect	100%
Endo Pharmaceuticals Inc.	Delaware	Indirect	100%
Endo TopFin Limited	Ireland	Indirect	100%
Endo U.S. Inc.	Delaware	Indirect	100%
Endo US Holdings Luxembourg I S.a r.l.	Luxembourg	Indirect	100%
Endo US Holdings Luxembourg II S.a r.l.	Luxembourg	Indirect	100%
Endo Ventures Limited	Ireland	Indirect	100%
Generics Bidco I, LLC (doing business as Par Pharmaceutical)	Delaware	Indirect	100%
Generics International (US Parent), Inc.	Delaware	Indirect	100%
Generics International (US) 2, Inc.	Delaware	Indirect	100%
Hawk Acquisition Ireland Limited	Ireland	Indirect	100%
JHP Group Holdings 2, Inc.	Delaware	Indirect	100%
JHP Group Holdings, LLC	Delaware	Indirect	100%
Luxembourg Endo Specialty Pharmaceuticals Holding I S.a r.l.	Luxembourg	Indirect	100%
Luxembourg Endo Specialty Pharmaceuticals Holding II S.a r.l.	Luxembourg	Indirect	100%
Paladin Labs Canadian Holding Inc.	Canada	Indirect	100%
Paladin Labs Inc.	Canada	Indirect	100%
Par Pharmaceutical 2, Inc.	Delaware	Indirect	100%
Par Pharmaceutical Companies, Inc.	Delaware	Indirect	100%
Par Pharmaceutical Holdings, Inc.	Delaware	Indirect	100%
Par Pharmaceutical, Inc. (doing business as Par Pharmaceutical)	New York	Indirect	100%
Par Sterile Products, LLC	Delaware	Indirect	100%
Par Two, Inc.	Delaware	Indirect	100%
Vintage Pharmaceuticals, LLC	Delaware	Indirect	100%

NOTE 29. SUBSEQUENT EVENTS

Over-the-counter (OTC) Products

We recently received notice from a competing pharmaceutical company that manufactures one of our products that it intends to seek approval to launch a competing OTC version of such product. We are currently assessing the potential likelihood, timing and impact of any such launch, which could result in, among other things, a reduction of our net sales of such product and/or certain asset impairment charges that could be material. In addition, the Company has identified certain triggering events for the three months ended March 31, 2019 related to certain intangible assets and goodwill that will require the Company to test these assets for impairment. This analysis, which we expect to complete in connection with our first quarter 2019 financial reporting close, is expected to result in certain impairment charges, the amounts of which could be material.

March 2019 Refinancing

In March 2019, the Group executed several transactions (the March 2019 Refinancing Transactions), which included:

- the entry into an amendment (the Revolving Credit Facility Amendment) to the Group's existing credit agreement, which was originally dated April 27, 2017 (the Credit Agreement);
- the issuance of $1,500.0 million of 7.50% Senior Secured Notes due 2027 (the 2027 Notes);
- the repurchase of $1,642.2 million aggregate principal amount of certain of the Group's senior unsecured notes for $1,500.0 million in cash, excluding accrued interest (the Notes Repurchases); and
- the solicitation of consents from the holders of the existing 7.25% Senior Notes due 2022 and 5.75% Senior Notes due 2022 (together, the Consent Notes) to certain amendments to the indentures governing such notes, which eliminated substantially all of the restrictive covenants, certain events of default and other provisions contained in each such indenture.

The Revolving Credit Facility Amendment amended the Credit Agreement to, among other things, (i) extend the maturity of the commitments under the Revolving Credit Facility from April 2022 to March 2024 (with the exception of $76.0 million of commitments that were not extended), (ii) provide greater covenant flexibility by increasing the maximum Secured Net Leverage Ratio described in the Financial Covenant (as defined in the Credit Agreement) from 3.50:1.00 to 4.50:1.00 and (iii) limit the scenarios under which such Financial Covenant will be tested.

The 2027 Notes were issued by Par Pharmaceutical, Inc. (PPI), a wholly-owned subsidiary of the Company, in a private offering to "qualified institutional buyers" (as defined in Rule 144A under the Securities Act) and outside the U.S. to non-U.S. persons in compliance with Regulation S under the Securities Act. The 2027 Notes are guaranteed on a senior secured basis by the Company and its subsidiaries that also guarantee the Credit Agreement (collectively, the Guarantors). The 2027 Notes are senior secured obligations of PPI and the Guarantors and are secured by the same collateral that secures the Credit Agreement and the Company's existing senior secured notes. Interest on the 2027 Notes is payable semiannually in arrears on April 1 and October 1 of each year, beginning on October 1, 2019.

The 2027 Notes will mature on April 1, 2027; however, the indenture governing these notes allows for redemption prior to maturity, in whole or in part, subject to certain restrictions and limitations described therein, in the following ways:

- Before April 1, 2022, the 2027 Notes may be redeemed, in whole or in part, by paying the sum of: (i) 100% of the principal amount being redeemed, (ii) an applicable make-whole premium as described in the indenture and (iii) accrued and unpaid interest, if any, to, but not including, the date of redemption.
- On or after April 1, 2022, the 2027 Notes may be redeemed, in whole or in part, at redemption prices set forth in the indenture, plus accrued and unpaid interest, if any, to, but not including, the date of redemption. The redemption prices for the 2027 Notes vary over time pursuant to a step-down schedule set forth in the indenture, beginning at 105.625% of the principal amount redeemed and decreasing to 100% by April 1, 2025.
- Before April 1, 2022, the 2027 Notes may be redeemed, in part (up to 35% of the principal amount outstanding) with the net cash proceeds from specified equity offerings at 107.500% of the principal amount redeemed, plus accrued and unpaid interest, if any, to, but not including, the date of redemption.

The 2027 Notes indenture contains covenants that, among other things, restrict the Group's ability and the ability of its Restricted Subsidiaries (as defined in the indenture) to incur certain additional indebtedness and issue preferred stock; make certain dividends, distributions, investments and other restricted payments; sell certain assets; enter into sale and leaseback transactions; agree to certain restrictions on the ability of restricted subsidiaries to make certain payments to the Group or any of its restricted subsidiaries; create certain liens; merge, consolidate or sell all or substantially all of the Group's assets; enter into certain transactions with affiliates or designate subsidiaries as unrestricted subsidiaries. These covenants are subject to a number of exceptions and qualifications, including the fall away or revision of certain of these covenants and release of collateral upon the 2027 Notes receiving investment grade credit ratings.

The Group used the net proceeds of the 2027 Notes and cash at bank and in-hand primarily to fund the Notes Repurchases and to pay certain premiums, fees and expenses related thereto. The Notes Repurchases were completed by Endo Finance LLC (Endo Finance), a wholly-owned subsidiary of the Group, pursuant to a tender offer to repurchase portions of the Company's outstanding 7.25% Senior Notes due 2022, 5.75% Senior Notes due 2022, 5.375% Senior Notes due 2023 and 6.00% Senior Notes due 2023. In connection with the Notes Repurchases, Endo Finance repurchased $1,642.2 million of senior unsecured note indebtedness, representing the aggregate principal amount repurchased, for $1,500.0 million in cash (including certain cash premiums related thereto). The $1,642.2 million aggregate repurchase amount consisted of (i) $389.9 million aggregate principal amount of the 7.25% Senior Notes due 2022, (ii) $517.5 million aggregate principal amount of the 5.75% Senior Notes due 2022, (iii) $539.6 million aggregate principal amount of the 5.375% Senior Notes due 2023 and (iv) $195.2 million aggregate principal amount of the 6.00% Senior Notes due 2023. The aggregate carrying amount of notes repurchased was $1,624.0 million. In conjunction with the Notes Repurchases, Endo Finance also solicited consents from holders of the Consent Notes to certain proposed amendments to the applicable indentures under which each series of Consent Notes were issued, which would eliminate substantially all restrictive covenants, certain events of default and certain other provisions contained in each such indenture. The proposed amendments were effected pursuant to a supplemental indenture to each such indenture executed by Endo Finance and the guarantors of the Consent Notes, which became operative upon the repurchase of at least the requisite consent amount of the applicable series of Consent Notes tendered.

The difference between the cash paid and the carrying amount of notes repurchased in the Notes Repurchases resulted in a $124.0 million gain recorded as Gain on extinguishment of debt in the Consolidated Profit and Loss Account. In connection with the March 2019 Refinancing Transactions, we also incurred costs and fees totaling $26.2 million, of which $4.2 million related to the Notes Repurchases, $19.1 million related to the 2027 Notes issuance and $2.9 million related to the Revolving Credit Facility Amendment. The costs incurred in connection with the Notes Repurchases were charged to expense in the first quarter of 2019 and recorded as an offset to the Gain on extinguishment of debt. The costs incurred in connection with the 2027 Notes issuance and the Revolving Credit Facility Amendment, together with previously deferred debt issuance costs associated with the Revolving Credit Facility, have been deferred and will be amortized as interest expense over the terms of the respective instruments.

NOTE 30. APPROVAL OF THE FINANCIAL STATEMENTS

The financial statements were approved by the directors on April 24, 2019.

ENDO INTERNATIONAL PLC
COMPANY RECONCILIATION OF SHAREHOLDERS' FUNDS
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017
(In thousands)

	Share Capital Presented as Equity	Share Premium	Profit and Loss Account	Other Reserves	Total Equity
BALANCE, January 1, 2017	$ 64	$ 6,140,580	$ (1,938,080)	$ 183,221	$ 4,385,785
Net loss	—	—	(2,434,352)	—	(2,434,352)
Share-based payment activity	—	—	—	50,149	50,149
Receipt of Endo International's shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	—	—	(2,078)	—	(2,078)
Other	6	(146)	—	—	(140)
BALANCE, DECEMBER 31, 2017	$ 70	$ 6,140,434	$ (4,374,510)	$ 233,370	$ 1,999,364
Net loss	—	—	(142,653)	—	(142,653)
Share-based payment activity	—	—	—	54,071	54,071
Option exercises	—	933	—	—	933
LTCI modification	—	14,936	—	—	14,936
Receipt of Endo International's shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	—	—	(5,375)	—	(5,375)
Other	(2)	71	—	(1)	68
BALANCE, DECEMBER 31, 2018	$ 68	$ 6,156,374	$ (4,522,538)	$ 287,440	$ 1,921,344

ENDO INTERNATIONAL PLC
COMPANY BALANCE SHEET
DECEMBER 31, 2018 AND 2017
(In thousands)

	Note	December 31, 2018	December 31, 2017
ASSETS			
Financial Fixed Assets			
Investment in subsidiaries	3	$ 1,989,676	$ 2,042,355
Current Assets			
Debtors - Prepayments and other debtors		4,604	796
Debtors - Amounts due from subsidiaries	4	52,191	34,541
Cash at bank and in hand		6,863	6,453
TOTAL ASSETS		$ 2,053,334	$ 2,084,145
EQUITY AND LIABILITIES			
Capital and Reserves			
Called up share capital presented as equity, $0.01 par value Euro deferred shares	7	$ 46	$ 48
Called up share capital presented as equity, $0.0001 par value ordinary shares	7	22	22
Share premium account	7	6,156,374	6,140,434
Other reserves	7	287,440	233,370
Profit and loss account	7	(4,522,538)	(4,374,510)
Total equity		$ 1,921,344	$ 1,999,364
Creditors (amounts falling due within one year)			
Intercompany loan payable	5	$ 97,675	$ 42,601
Amounts due to subsidiaries	6	26,855	40,693
Accruals and other creditors		7,460	1,487
Total for creditors		$ 131,990	$ 84,781
TOTAL EQUITY AND LIABILITIES		$ 2,053,334	$ 2,084,145

The Notes to the Company Balance Sheet are an integral part of this statement.
The financial statements were approved by the Board of Directors on April 24, 2019 and signed on its behalf by:

/s/ Roger H. Kimmel
Roger H. Kimmel
Chairman

/s/ Paul Campanelli
Paul Campanelli
Director

NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Preparation

The financial statements have been prepared on a going concern basis and in accordance with the Companies Act 2014, and Financial Reporting Standard 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland*. The accompanying balance sheet of Endo International plc (the Company) is presented on a stand-alone basis, including related party transactions. The financial statements are presented in United States (U.S.) dollars, which is the Company's functional and presentation currency. All values are rounded to the nearest thousand U.S. dollars except when otherwise indicated.

The financial statements are prepared under the historical cost convention. The accounting policies which follow set out those policies which apply in preparing the financial statements for the year ended December 31, 2018. The Company has taken advantage of the following disclosure exemptions under FRS 102:

- the requirements of section 4 Statement of Financial Position - Paragraph 4.12 (a) (iv),
- the requirements of section 7 Statement of Cash Flows and Section 3 Financial Statement Presentation paragraph 3.17(d),
- the requirements of Section 26 Share based Payment: paragraph 26.18 (b), 26.19 to 26.21 and 26.23
- the requirements of Section 33 Related Party Disclosures, paragraph 33.7, and
- the requirements of Section 304 of the Companies Act 2014

Critical Accounting Judgments and Estimation Uncertainty

The preparation of the Company's financial statements requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, turnover and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates and judgments and methodologies, including those related to its investments in subsidiaries and share-based compensation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

Employees and Directors

The Company had no employees during the year. The Company's directors are not employees but are remunerated for their service by the parent company. See Note 26. Directors' Remuneration of the accompanying Consolidated Financial Statements included in this report for a summary of their remuneration.

Related Party Transactions

The Company has not disclosed any other related party transactions as it has availed of the exemption available under the provisions of FRS 102 Section 33.1A ''Related Party Disclosures'' which exempts disclosure of transactions entered into between two or more members of a group, provided that any subsidiary which is a party to the transaction is wholly owned by a member of that group.

Investment in Subsidiaries

Investment in subsidiaries is stated in the Company's Balance Sheet at cost less any return of capital, unless it has been impaired in which case it is carried at net of any impairment loss recognized.

Share Based Payments

Endo International plc and its subsidiaries operate a number of share based payment plans, the details of which are presented in Note 16. Share-Based Compensation to the Consolidated Financial Statements. The share based payment expense associated with the share plans is recognized as an expense by the group entity, which employs and receives the services in exchange for the share based compensation. In these Company only accounts, the profit and loss account is charged with only the expense related to the services received directly by the Company. The cost for equity awards granted to the Company's subsidiaries' employees represents additional capital contributions by the Company to its subsidiaries. An additional investment in subsidiaries has been recorded in respect of those equity awards granted to the Company's subsidiaries' employees, with a corresponding increase in the Company's shareholder funds. The additional capital contribution is based on the fair value at the grant date of the equity awards issued, allocated over the life of the underlying grant's vesting period.

Share Premium

The difference between the proceeds received on issue of shares and the nominal value of the shares is credited to the share premium account.

Profit and loss account

In accordance with Section 304 of the Companies Act 2014, the Company is availing of the exemption from presenting the individual profit and loss account. Endo International plc's losses for the years ended December 31, 2018 and 2017 were $142.7 million and $2,434.4 million, respectively. No other comprehensive income or losses were applicable for the years ended December 31, 2018 and 2017.

Share Repurchases

The Company accounts for the repurchase of ordinary shares at par value. Under applicable Irish law, ordinary shares repurchased are retired and not displayed separately as treasury stock. Upon retirement of the ordinary shares, the Company records the weighted average cost of such ordinary shares as an adjustment to its consolidated Profit and loss account in the Company's Balance Sheet.

Foreign Currency

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within ''Other income, net'' in the Consolidated Profit and Loss Account.

Taxation

Deferred tax is recognised in respect of all timing differences which are differences between taxable profits and total comprehensive income that arise from the inclusion of income and expenses in tax assessments in periods different from those in which they are recognised in the financial statements, except that unrelieved tax losses and other deferred tax assets are recognised only to the extent that the directors consider that it probable that they will be recovered against the reversal of deferred tax liabilities or other future taxable profits. Deferred tax is measured on an undiscounted basis at the tax rates that are expected to apply in the periods in which timing differences reverse, based on tax rates and laws enacted or substantively enacted at the balance sheet date. The Company accounts for uncertain tax positions using a ''more-likely-than-not'' threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates this tax position on a quarterly basis. The Company also accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense.

NOTE 2. HISTORY AND DESCRIPTION OF THE COMPANY

Endo International plc was incorporated in Ireland on October 31, 2013 as a private limited company and re-registered effective February 18, 2014 as a public limited company. It was established for the purpose of facilitating the business combination between Endo Health Solutions Inc. (EHSI) and Paladin Labs Inc. (Paladin).

On February 28, 2014, pursuant to an arrangement agreement, dated November 5, 2013 (the Arrangement Agreement), among EHSI, Endo International Limited, Endo Limited (formerly known as Sportwell II Limited), Endo U.S. Inc. (formerly known as ULU Acquisition Corp.), RDS Merger Sub, LLC (Merger Sub), 8312214 Canada Inc. and Paladin (a) Endo International Limited indirectly acquired all of the outstanding common shares of Paladin pursuant to a plan of arrangement under Canadian law (the Arrangement); and (b) Merger Sub merged with and into EHSI, with EHSI as the surviving corporation in the merger (the Merger and, together with the Arrangement, the Transactions). Following consummation of the Transactions, each of EHSI and Paladin became indirect wholly owned subsidiaries of Endo International plc.

Pursuant to the Arrangement, (a) former Paladin shareholders received C$1.16 in cash, 1.6331 newly issued Endo International ordinary shares and one common share of Knight Therapeutics Inc., a newly formed corporation incorporated under the laws of Canada that was separated from Paladin as part of the Transactions, in exchange for each Paladin common share held by such former shareholders; (b) all options to acquire Paladin common shares were settled on a cashless exercise basis for Endo International ordinary shares and common shares of Knight Therapeutics Inc. in an amount reflecting the arrangement consideration; and (c) unvested rights to receive additional common shares under Paladin's share purchase plan were settled for a cash amount based on the Paladin common share price immediately prior to the effective time of the Arrangement. At the effective time of the Merger, each share of EHSI common stock was cancelled and automatically converted into the right to receive one Endo International plc ordinary share. Immediately following the closing of the transaction, former EHSI shareholders owned approximately 79% of Endo International plc, and former Paladin shareholders owned approximately 21%.

Endo International plc is an Ireland-domiciled, global specialty pharmaceutical company focused on branded and generic pharmaceuticals. Endo International plc aims to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of branded and generic drugs to meet patients' needs. The Company's corporate headquarters are located at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland. The Company's headquarters for its United States operations is based in Malvern, Pennsylvania.

NOTE 3. INVESTMENT IN SUBSIDIARIES

A reconciliation of the change in the Investment in Subsidiaries balance from December 31, 2016 to December 31, 2018 is as follows (in thousands):

	Investment in Subsidiaries
Balance - December 31, 2016, at cost	$ 4,405,852
Capital contribution in respect of share-based payment plans	45,931
Impairment	(2,396,000)
Other	(13,428)
Balance - December 31, 2017, at cost	$ 2,042,355
Capital contribution in respect of share-based payment plans	52,321
Impairment	(105,000)
Balance - December 31, 2018, at cost	$ 1,989,676

The Company was re-registered as a public limited company effective February 18, 2014 and Endo International plc was formed. Refer to Note 2. History and Description of the Company for a description of this transaction.

On January 29, 2015, the Company, through an indirect wholly owned subsidiary, acquired all of the outstanding shares of common stock of Auxilium. The consideration included 18,609,835 ordinary shares valued at $1.52 billion. On June 10, 2015, the Company completed the sale of 27,627,628 ordinary shares for gross proceeds of $2.24 billion, including fees, in order to finance a portion of the Par acquisition. On September 25, 2015, the Company, through an indirectly wholly owned subsidiary, acquired Par. The consideration included 18,069,899 ordinary shares valued at $1.33 billion.

During the years ended December 31, 2018 and 2017, the Company identified certain trigger events indicating a potential impairment of its Investment in subsidiaries balance and initiated an Investment in subsidiaries impairment analysis as of December 31, 2018 and 2017. As a result of this analysis, the Company determined that the net book value of its Investment in subsidiaries asset exceeded its estimated fair value. As part of the impairment analysis, the Company recorded non-cash impairment charges of $0.1 billion and $2.4 billion in the Profit and loss accounts for the years ended December 31, 2018 and 2017, respectively, representing the difference between the estimated fair value of the Company's Investment in subsidiaries and its respective book value. Both the 2018 and 2017 impairments were primarily driven by a combination of factors, including a sustained downturn in Endo's stock price, increased buying power from the continued consolidation of the Company's generic business customer base, a significant change in the value derived from the level and frequency of anticipated pricing opportunities in the future and increased levels of competition, particularly in the Company's U.S. Generics reporting unit, due to the entry of new low cost competitors and accelerated FDA ANDA approvals. If the estimated control premium for the impairment analysis had increased or decreased from management's estimate by 1%, the impairment of the Investment in subsidiaries balance would have changed by $16.4 million and $17.3 million for the years ended December 31, 2018 and 2017, respectively.

Other for the year ended December 31, 2017 consists primarily of dividends totaling $16.0 million from the Company's consolidated subsidiaries.

NOTE 4. AMOUNTS DUE FROM SUBSIDIARIES

Amounts due from subsidiaries of $52.2 million and $34.5 million at December 31, 2018 and 2017, respectively, are non-interest bearing and payable on demand.

NOTE 5. INTERCOMPANY LOAN PAYABLE

On February 28, 2014, the Company issued $24.7 million in aggregate principal amount of a non-interest bearing note to an affiliate. The loan is due upon the earlier of the expiration of five years from the issuance date or upon written demand by the affiliate. On December 20, 2017, the Company issued $17.9 million in aggregate principal amount of a non-interest bearing note to an affiliate. The loan is due upon the earlier of the expiration of thirty years from the issuance date or upon written demand by the affiliate. On June 22, 2018, the Company issued $30.1 million in aggregate principal amount of a non-interest bearing note to an affiliate. The loan is due upon the earlier of the expiration of thirty years from the issuance date or upon written demand by the affiliate. On December 24, 2018, the Company issued $25.0 million in aggregate principal amount of a non-interest bearing note to an affiliate. The loan is due up on the earlier of of the expiration of thirty years from the issuance date or upon written demand by the affiliate.

NOTE 6. AMOUNTS DUE TO SUBSIDIARIES

Amounts due to subsidiaries of $26.9 million and $40.7 million at December 31, 2018 and 2017, respectively, are non-interest bearing and payable on demand.

NOTE 7. SHARE CAPITAL

Share Capital consists of the following for the year ended December 31, 2018 (in thousands):

	2018
Authorized:	
4,000,000 Euro deferred shares of $0.01 par value (4,000,000 issued and outstanding)	$ 40
1,000,000,000 ordinary shares of $0.0001 par value (224,382,791 issued and outstanding)	100
Total share capital	$ 140
Allotted, called-up and fully paid equity:	
BALANCE, DECEMBER 31, 2016	$ 64
Other	6
BALANCE, DECEMBER 31, 2017	$ 70
Other	(2)
BALANCE, DECEMBER 31, 2018	$ 68

Share Repurchase Program

The Company has broad shareholder authority to conduct share repurchases of its ordinary shares, as its shareholders granted to the Company a general authority (the 2014 Share Buyback Authority) to make overseas market purchases (as defined by section 212 of the Irish Companies Act 1990 (the 1990 Act)) of shares of the Company on such terms and conditions as the Company's Board of Directors may approve, but subject to the provisions of the 1990 Act and certain other provisions.

Pursuant to the 2014 Share Buyback Authority, in April 2015, the Company's Board of Directors approved a share buyback program (the 2015 Share Buyback Program). The 2015 Share Buyback Program authorizes the Company to redeem in the aggregate $2.5 billion of its outstanding ordinary shares. In accordance with Irish Law and the Company’s Articles of Association, all ordinary shares redeemed shall be cancelled upon redemption.

In November 2015, the Company entered into a program to repurchase up to $250.0 million of its ordinary shares under the 2015 Share Buyback Program. The Company purchased approximately 4.4 million of its ordinary shares during November 2015 totaling $250.0 million, not including related fees.

Stock Incentive Plans

In June 2015, the Company's shareholders approved the 2015 Stock Incentive Plan (the 2015 Plan), which has subsequently been amended, as approved by the Company's shareholders, on multiple occasions, including in 2017 and 2018. Under the 2015 Plan, stock options (including incentive stock options), stock appreciation rights, restricted stock awards, performance awards and other share- or cash-based awards may be issued at the discretion of the Board of Directors from time to time. No ordinary shares are to be granted under previously approved plans, including the Company's 2000, 2004, 2007, 2010 and Assumed Stock Incentive Plans. All awards previously granted and outstanding under these prior plans remain subject to the terms of those prior plans.

At December 31, 2018, approximately 5.5 million ordinary shares were reserved for future grants under the 2015 Plan. As of December 31, 2018, stock options, restricted stock awards, performance stock units and restricted stock units have been granted under the stock incentive plans.

Share premium account

This reserve records the amount above the nominal value received for shares sold, less transaction costs.

Other reserves

This reserve is used to recognise the value of equity-settled share-based payments provided to employees of the group as part of their remuneration.

NOTE 8. CONTINGENCIES

The Company and certain of its subsidiaries are involved in various claims, legal proceedings and governmental investigations that arise from time to time in the ordinary course of business, including relating to product liability, intellectual property, regulatory compliance and commercial matters. While the Company cannot predict the outcome of these ongoing legal proceedings and the Company and its subsidiaries intend to defend vigorously its and their position, an adverse outcome in any of these proceedings could have a material adverse effect on the Company's current and future financial position, results of operations and cash flows. See Note 13. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report for additional information.

NOTE 9. GUARANTEES

On February 28, 2014, Endo International plc became the ultimate parent company and EHSI became a stand-alone subsidiary in accordance with the Arrangement Agreement and as further described above in Note 2. History and Description of the Company. As part of the Arrangement Agreement, the guarantee structure was updated to reflect the newly created legal structure under which Endo International plc assumed the obligations of EHSI as issuer or guarantor under the various indentures covering the outstanding Convertible Notes of EHSI.

In accordance with the provisions of Section 357 of the Companies Act 2014, the Company has guaranteed the liabilities of certain of its Irish subsidiaries in respect of the year ended December 31, 2018 in order to avail of the exemption from the filing provisions under Section 347 and 348 of the Companies Act 2014. These Irish subsidiaries are Endo Ventures Limited and Endo DAC.

The Company is also a guarantor on both Dublin leases at Minerva House and Simmonscourt House, respectively, both with an address at Simmonscourt Road, Dublin 4, Ireland.

Endo International plc entered into a credit agreement (the 2017 Credit Agreement) on April 27, 2017 as a guarantor, together with its subsidiaries Endo Luxembourg Finance Company I S.à r.l., and Endo LLC as borrowers, the lenders party thereto and JPMorgan Chase Bank, N.A., as administrative agent, issuing bank and swingline lender. The 2017 Credit Agreement provided for (i) a five-year revolving credit facility in a principal amount of approximately $1,000.0 million (the 2017 Revolving Credit Facility) and (ii) a seven-year term loan facility in a principal amount of approximately $3,415.0 million (the 2017 Term Loan Facility); provided that each of the 2017 Revolving Credit Facility and the 2017 Term Loan Facility may mature prior to its respective stated maturity in the event that certain of our senior notes are not refinanced or repaid in full prior to the date that is 91 days before the stated maturity of such notes. In March 2019, the Company entered into an amendment (the Revolving Credit Facility Amendment) to the 2017 Credit Agreement. The Revolving Credit Facility Amendment amended the Credit Agreement to, among other things, (i) extend the maturity of the commitments under the 2017 Revolving Credit Facility from April 2022 to March 2024 (with the exception of $76.0 million of commitments that were not extended), (ii) provide greater covenant flexibility by increasing the maximum Secured Net Leverage Ratio described in the Financial Covenant (as defined in the 2017 Credit Agreement) from 3.50:1.00 to 4.50:1.00 and (iii) limit the scenarios under which such Financial Covenant will be tested. On April 27, 2017, Endo DAC, Endo Finance LLC and Endo Finco Inc. (collectively, the Issuers) issued $300.0 million in aggregate principal amount of 5.875% senior secured notes due 2024 (the 2024 Notes). Further, on March 14, 2019, Par Pharmaceutical, Inc., a wholly owned subsidiary of the Company, issued

$1.500.0 million in aggregate principal amount of 7.500% senior secured notes due 2027 (the 2027 Notes). Both the 2024 Notes and the 2027 Notes are guaranteed by Endo International plc and its subsidiaries that also guarantee the 2017 Credit Agreement.

NOTE 10. AUDITORS' REMUNERATION

Total auditors' remuneration paid to PricewaterhouseCoopers and its affiliated firms for the years ended December 31, 2018 and 2017 were as follows (in thousands):

	2017	2016
Audit of the Company's individual accounts	$ 115	$ 108
Audit-related fees	—	—
Tax fees	—	—
Total auditors' remuneration	$ 115	$ 108

See Note 27. Auditors' Remuneration of the accompanying Consolidated Financial Statements included in this report for additional information regarding fees paid to the auditors by the Company.

NOTE 11. APPROVAL OF THE FINANCIAL STATEMENTS

The financial statements were approved and authorized for issue by the directors on April 24, 2019.

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