

ENDO INTERNATIONAL PUBLIC LIMITED COMPANY

Directors' Report and Financial Statements

For the Year Ended December 31, 2019

ENDO INTERNATIONAL PLC
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DIRECTORS AND OTHER INFORMATION

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AUDITORS	PricewaterhouseCoopers, Chartered Accountants and Statutory Audit Firm, One Spencer Dock, North Wall Quay, Dublin 1.

DIRECTORS' REPORT

For the Year Ended December 31, 2019

The directors present their report and audited Consolidated Financial Statements for the year ended December 31, 2019.

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 specialty branded and generics pharmaceutical company. 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. Endo International plc is a holding company that conducts its operations through its subsidiaries.

Our ordinary shares are traded on the Nasdaq Global Select 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 of \$0.0001 per share). In addition, we have 4,000,000 euro deferred shares outstanding (par value of \$0.01 per share).

The address of Endo International plc’s headquarters is Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland (telephone number: 011-353-1-268-2000).

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 invest in products or product candidates that have inherent scientific, regulatory, legal and technical complexities and market such products under recognizable brand names that are trademarked. For products we develop for the United States (U.S.) market, 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). Upon U.S. approval, patents included in such NDAs 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.

For generic products, which are the pharmaceutical and therapeutic equivalents of branded products and 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 refers to a generic product for which the Abbreviated New Drug Application (ANDA) containing a patent challenge (or Paragraph IV certification) to the corresponding branded product’s FDA Orange Book-listed patents was the first to be filed with the FDA. In the U.S., manufacturers that launch first-to-file products, after success in litigating or otherwise resolving related patent challenges, and receive final FDA approval have the opportunity for 180 days of generic marketing exclusivity from competing generic products other than authorized generics. 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. This can occur, for example, when a generic product is difficult to formulate or manufacture. First-to-market products allow manufacturers to mitigate risks from competitive pressures commonly associated with commoditized generic products.

The four reportable business segments in which we operate are: (1) Branded Pharmaceuticals, (2) Sterile Injectables, (3) Generic Pharmaceuticals and (4) International Pharmaceuticals. Additional information about our reportable business segments is included throughout this Part I. The results of operations of our reportable business segments are discussed in "Results of Operations." Across all of our reportable business segments, we generated total turnover of \$2.91 billion and \$2.95 billion in 2019 and 2018 respectively.

In December 2019, the novel strain of coronavirus referred to as COVID-19 (COVID-19) was reported to have surfaced in Wuhan, China. In March 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. We are closely monitoring the impact of COVID-19 on all aspects of our business, the pharmaceutical industry and the economy as a whole, including how it has and will continue to impact our workforce, our customers and the patients they serve, our manufacturing and supply chain operations, our research and development (R&D) programs and regulatory approval processes and our liquidity and access to capital.

Products Overview

Branded Pharmaceuticals

The following table displays the turnover from external customers of our Branded Pharmaceuticals segment for the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
<i>Specialty Products:</i>		
XIAFLEX®	\$ 327,638	\$ 264,638
SUPPRELIN® LA	86,797	81,707
Other Specialty (1)	105,241	98,230
Total Specialty Products	\$ 519,676	\$ 444,575
<i>Established Products:</i>		
PERCOCET®	\$ 116,012	\$ 122,901
TESTOPEL®	55,244	58,377
Other Established (2)	164,470	236,979
Total Established Products	\$ 335,726	\$ 418,257
Total Branded Pharmaceuticals (3)	\$ 855,402	\$ 862,832

- (1) Products included within Other Specialty are NASCOBAL® Nasal Spray and AVEED®. Beginning with our first-quarter 2019 reporting, TESTOPEL®, which was previously included in Other Specialty, has been reclassified and is now included in the Established Products portfolio for all periods presented.
- (2) Products included within Other Established include, but are not limited to, LIDODERM®, EDEX® and VOLTAREN® Gel.
- (3) Individual products presented above represent the top two performing products in each product category for the year ended December 31, 2019 and/or any product having turnover in excess of \$100 million during any of the years ended December 31, 2019 or 2018 or \$25 million during any quarterly period in 2019 or 2018.

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 portfolio include the following:

- XIAFLEX®, which is the first and currently the only FDA-approved non-surgical treatment for DC (for adult patients with an abnormal buildup of collagen in the fingers that limits or disables hand function). It is also the first and currently the only FDA-approved non-surgical treatment for PD (for adult men with a collagen plaque and a penile curvature deformity of thirty degrees or greater at the start of therapy).
- 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 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.
- AVEED[®], which is a novel, long-acting testosterone undecanoate for injection for the treatment of hypogonadism that is dosed only five times per year after the first month of therapy.

Established Products Portfolio

This 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 the treatment of hypogonadism. Key product offerings in this portfolio include, among others, the following:

- PERCOCET[®], which is an opioid analgesic approved for the treatment of moderate-to-moderately-severe pain.
- TESTOPEL[®], which is a unique, long-acting implantable pellet indicated for TRT in conditions associated with a deficiency or absence of endogenous testosterone.
- LIDODERM[®], which is a topical patch product containing lidocaine that is 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).
- 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.
- VOLTAREN[®] Gel, which is a topical prescription treatment for the relief of joint pain associated with osteoarthritis in the knees, ankles, feet, elbows, wrists and hands.

The Group's pain products, including opioid products, are managed as mature brands and are not and have not been actively promoted for years. In December 2016, the Group announced the elimination of its entire U.S. pain product field sales force.

Sterile Injectables

The following table displays the turnover from external customers of our Sterile Injectables segment for the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
VASOSTRICT [®]	\$ 531,737	\$ 453,767
ADRENALIN [®]	179,295	143,489
Ertapenem for injection.....	104,679	57,668
APLISOL [®]	61,826	64,913
Other Sterile Injectables (1)	185,594	209,729
Total Sterile Injectables (2).....	<u>\$ 1,063,131</u>	<u>\$ 929,566</u>

(1) Products included within Other Sterile Injectables include ephedrine sulfate injection, treprostinil for injection and others.

(2) Individual products presented above represent the top two performing products within the Sterile Injectables segment for the year ended December 31, 2019 and/or any product having turnover in excess of \$100 million during any of the years ended December 31, 2019 or 2018 or \$25 million during any quarterly period in 2019 or 2018.

The 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. Our sterile injectables products are manufactured in sterile facilities in vial dosages and are 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 the first and currently the only vasopressin injection with an NDA approved by the FDA.
- 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 (Merck) 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.
- Treprostinil for injection, which is used for the treatment of pulmonary arterial hypertension.

Generic Pharmaceuticals

The Generic Pharmaceuticals segment includes a product portfolio of approximately 150 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 pharmaceutical 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 products are the pharmaceutical and therapeutic equivalents of branded products and are generally marketed under their generic (chemical) names rather than their 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 product 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 products licensed by brand drug companies under an NDA and marketed as generics. Authorized generics do not face the same 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 generic versions of our branded products including, for example, lidocaine patch 5% (LIDODERM[®]). We also aim to be a partner of choice to large companies seeking authorized generic distributors for their branded products. For example, in April 2019, we launched albuterol sulfate HFA inhalation aerosol (the authorized generic of Merck's Proventil[®]) and, in July 2018, we launched colchicine tablets (the authorized generic of Takeda Pharmaceuticals U.S.A., Inc.'s (Takeda) Colcrys[®]).

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 Labs Inc. (Paladin). The key products of this segment 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, which was sold in October 2017 and consisted of Grupo Farmacéutico Somar, S.A.P.I. de C.V. (Somar).

Select Products in Development

XIAFLEX[®]

XIAFLEX[®], which contains the enzyme collagenase clostridium histolyticum (CCH), is currently approved by the FDA and marketed in the U.S. for the treatment of both DC and PD (two separate medical therapeutic indications). As further described in Note 11. License and Collaboration Agreements, we in-licensed certain rights related to CCH pursuant to which we may, among other things, develop our XIAFLEX[®] product or other product candidates containing CCH for potential additional medical therapeutics indications.

In early 2020, we announced that we had initiated our XIAFLEX[®] development programs for the treatment of plantar fibromatosis and adhesive capsulitis.

Collagenase Clostridium Histolyticum - Medical Aesthetics

Our license rights relating to CCH also permit us to develop product candidates containing CCH for certain medical aesthetics indications. For example, we have rights to develop and globally market CCH for the treatment of cellulite. We are currently progressing our cellulite treatment development program. While based on the same enzyme, CCH for the treatment of cellulite is a different formulation and presentation with a different treatment regimen. In November 2019, we announced the FDA's acceptance for review of the original BLA for CCH for the treatment of cellulite in the buttocks. The BLA is supported by the results of the RELEASE-1 and RELEASE-2 Phase 3 studies, as well as a clinical program. Trial subjects receiving CCH for the treatment of cellulite 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 for the treatment of cellulite 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. The Prescription Drug User Fee Act (PDUFA) date, or target action date, for the BLA has been set for July 6, 2020.

Subject to certain limitations, we have the right to further develop this same and/or other product candidates containing CCH for additional medical aesthetics indications.

Other

Our remaining pipeline consists mainly of a variety of product candidates in our Sterile Injectables and Generic Pharmaceuticals 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 as well as products that meet the evolving needs of hospitals and health systems. 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 Sterile Injectables business, we also focus on developing branded injectable products with inherent scientific, regulatory, legal and technical complexities, as well as developing other dosage forms and technologies.

As of December 31, 2019, these two segments were actively pursuing approximately 110 product candidates, which included approximately 65 ANDAs pending with the FDA. Of the 65 ANDAs, approximately half represent first-to-file opportunities or first-to-market opportunities. These numbers do not include five sterile injectable product candidates relating to a second-quarter 2018 development, license and commercialization agreement with 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.

Major Customers

We primarily sell our branded and generic products 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 care organizations (MCOs). Customers in the managed care market include health maintenance organizations, nursing homes, hospitals, clinics, pharmacy benefit management companies and mail order customers. Our current customer group reflects significant consolidation in recent years, marked by mergers and acquisitions and other alliances. Total turnover from direct customers that accounted for 10% or more of our total consolidated turnover during the years ended December 31, 2019 and 2018 are as follows:

	<u>2019</u>	<u>2018</u>
AmerisourceBergen Corporation	34%	32%
McKesson Corporation	26%	27%
Cardinal Health, Inc.	25%	26%

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

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.

Competition

Branded Products

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

We compete principally through targeted product development and through our acquisition and in-licensing strategies, where we face intense competition as a result of the limited number of assets available and the number of competitors bidding on such assets. In addition to product development and acquisitions, other competitive factors with respect to branded products include product efficacy, safety, ease of use, price, demonstrated cost-effectiveness, marketing effectiveness, service, reputation and access to technical information.

Branded products often must compete with therapeutically similar branded or generic products or with generic equivalents. Such competition frequently increases over time. For example, if competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products could be subject to progressive price reductions and/or decreased volume of sales. To successfully compete for business, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care. Accordingly, we face pressure to continually seek out technological innovations and to market our products effectively.

Manufacturers of generic products typically invest far less in R&D than research-based companies and can therefore 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 lower prices, generic versions, where available, may be substituted by pharmacies or required in preference to branded versions under third-party reimbursement programs.

Branded Pharmaceuticals

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

Several of this segment's products, such as PERCOCET[®], TESTOPEL[®] and LIDODERM[®], face generic and/or other forms of competition. The degree of generic and/or other competition facing this segment could increase in the future.

Sterile Injectables

This segment's major competitors, including Hospira, Inc. (a subsidiary of Pfizer Inc.), Fresenius Kabi USA, LLC (Fresenius), Mylan and Hikma Pharmaceuticals PLC, vary by product. A significant portion of our sales, including sales to hospitals, clinics and long-term care facilities in the U.S., are controlled by a relatively small number of GPOs, including HealthTrust Purchasing Group, L.P., 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.

Generic Products

Generic products generally face intense competition from branded equivalents, other generic equivalents (including authorized generics) and therapeutically similar branded or generic products. Our major competitors, including Teva Pharmaceutical Industries Limited, Mylan, Sandoz (a division of Novartis) and Amneal Pharmaceuticals, Inc. (Amneal), among others, vary by product.

Consolidations of our customer base described above under the heading “Major Customers” have resulted in increased pricing and other competitive pressures on pharmaceutical companies, including us. Additionally, the emergence of large buying groups representing independent retail pharmacies and other distributors and the prevalence and influence of MCOs and similar institutions have increased the negotiating power of these groups, enabling them to attempt to extract various demands, including without limitation price discounts, rebates and other restrictive pricing terms. These competitive trends could continue in the future and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 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. For additional detail, see “Our Competitive Strengths - Focus on the differentiated products of our sterile injectables and generics portfolios.”

Even if we are successful in launching generic products with statutory generic exclusivity, competitors may enter the market when such exclusivity periods expire, resulting in significant price declines. Consequently, maintaining profitable operations 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. For additional detail, see “Our Competitive Strengths - Operational excellence.”

Seasonality

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

Patents, Trademarks, Licenses and Proprietary Property

We regard the protection of patents and other enforceable intellectual property rights that we own or license as critical to our business and competitive position. Accordingly, we rely on patent, trade secret and copyright law, as well as nondisclosure and other contractual arrangements, to protect our intellectual property. We have a portfolio of patents and patent applications owned or licensed by us that cover aspects of our products. These patents and applications generally include claims directed to the compounds and/or methods of using the compounds, formulations of the compounds, pharmaceutical salt forms of the compounds or methods of manufacturing the compounds. Our policy is to pursue patent applications on inventions that we believe are commercially important to the development and growth of our business. Certain patents relating to products that are the subject of approved NDAs are listed in the U.S. FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (Orange Book). The table below contains a list from the Orange Book of patent expiration dates for certain products we market.

The Orange Book does not include a listing of patents related to biological products. Included in the table are certain products for which we own or license a BLA along with the date of expiration of certain relevant patents or regulatory exclusivity. In addition, we may have other relevant regulatory protection or patents that may extend beyond the expiration date listed in the table below. We may also obtain further patents or additional regulatory or patent exclusivity for one or more indications for a product in the future.

As of February 18, 2020, we held approximately: 234 U.S. issued patents, 36 U.S. patent applications pending, 454 foreign issued patents and 71 foreign patent applications pending. In addition, as of February 18, 2020, we had licenses for approximately 46 U.S. issued patents, 11 U.S. patent applications pending, 171 foreign issued patents and 64 foreign patent applications pending. The following table sets forth, as of February 18, 2020, the year of expiration relating to certain of our products:

Relevant Product	Patent Expiration (1)(2)
VASOSTRICT [®]	2035
XIAFLEX [®]	2028
ADRENALIN [®]	2035
NASCOBAL [®] Nasal Spray	2024
AVEED [®]	2027

- (1) Our license agreements for the patents in the table above extend to or beyond the patent expiration dates. See Note 11. License and Collaboration Agreements for additional discussion about certain license agreements.
- (2) The expiration of a basic product patent or loss of patent protection resulting from a legal challenge normally results in significant competition from generic products or biosimilars against the originally patented product and can result in a significant reduction in turnover for that product in a very short period of time. In some cases, however, we can continue to obtain commercial benefits from product manufacturing trade secrets, patents on uses for products, patents on processes and intermediates for the economical manufacture of the active ingredients or patents for special formulations of the product or delivery mechanisms.

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. To achieve a competitive position, we also rely on trade secrets, non-patented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable. Many of our products are sold under trademarks. We also rely on confidentiality agreements with our employees, consultants and other parties to protect, among other things, trade secrets and other proprietary information.

There can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition or that our confidentiality 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.

Additionally, any pending or future patent applications made by us or our subsidiaries, our license partners or entities we may acquire in the future are subject to risks and uncertainties. The coverage claimed in any such patent applications could be significantly reduced before the patent is issued and there can be no assurance that any such applications 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 U.S. Patent and Trademark Office (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. See Principal Risks - “Our ability to protect and maintain our proprietary and licensed third party technology, which is vital to our business, is uncertain.”

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 14. Commitments and Contingencies.

Service Agreements

We contract with various third parties to provide certain critical services including manufacturing, supply, warehousing, distribution, customer service, certain financial functions, certain R&D activities and medical affairs, among others.

Refer to Note 11. License and Collaboration Agreements and Note 14. Commitments and Contingencies for additional information.

We primarily purchase our raw materials for the production and development of our products in the open market from third party suppliers. We attempt, when possible, to mitigate our raw material supply risks through stock management and alternative sourcing strategies. However, some raw materials are only available from one source. 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 R&D 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. Refer to Note 11. License and Collaboration Agreements for additional information.

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 business, financial condition, results of operations or cash flows.

Employees

As of February 18, 2020, we have 3,172 employees, of which 365 are engaged in R&D and regulatory work, 400 in sales and marketing, 1,243 in manufacturing, 636 in quality assurance and 528 in general and administrative capacities. With the exception of certain production personnel in our Rochester, Michigan manufacturing facility, our employees are generally not represented by unions. We believe that our relations with our employees are good.

Review of the Performance of the Business

Overview

This executive summary provides 2019 highlights from the results of operations that follow:

- Total turnover in 2019 decreased 1% to \$2,914.4 million compared to \$2,947.1 million in 2018 as strong performance from our Sterile Injectables segment and our Branded Pharmaceuticals segment's Specialty Products portfolio was more than offset by declines in our Branded Pharmaceuticals segment's Established Products portfolio and both our Generic Pharmaceuticals and International Pharmaceuticals segments.
- Gross margin percentage in 2019 increased to 46.2% from 44.6% in 2018, reflecting the impact of changes in product mix to higher margin Sterile Injectables and Specialty Products from lower margin Generic Pharmaceuticals and Established Products, as well as reductions to amortization expense and expenses related to retention and separation benefits and other cost reduction initiatives, partially offset by the unfavorable impact of increased sales of certain lower margin authorized generic products launched in the third quarter of 2018.
- Asset impairment charges in 2019 decreased to \$526.1 million from \$916.9 million in 2018.
- Loss from continuing operations in 2019 was \$343.1 million, compared to \$961.8 million in 2018.

Additionally, the following summary highlights certain key events that occurred during 2019:

- In November 2019, we announced the FDA's acceptance for review of the original BLA for CCH for the treatment of cellulite in the buttocks. The BLA is supported by the results of the RELEASE-1 and RELEASE-2 Phase 3 studies, as well as a clinical program. The PDUFA date, or target action date, for the BLA has been set for July 6, 2020.
- In March 2019, we completed a series of refinancing transactions that were intended to extend our debt maturity profile and provide greater covenant flexibility, which resulted in a net gain on extinguishment of debt of \$119.8 million. These transactions are collectively referred to herein as the March 2019 Refinancing Transactions and are further described in Note 13. Debt.
- As a result of the Group's lawsuit against the FDA challenging its interim policy authorizing bulk compounding of pharmaceuticals, the FDA evaluated whether there is a clinical need to compound vasopressin under Section 503B of the FFDCA. In March 2019, the FDA determined that there is no such clinical need. As a result, the bulk compounding of vasopressin is impermissible under Section 503B of the FFDCA unless the FDA were to add vasopressin to its drug shortage list. The FDA's decision was upheld by the U.S. District Court for the District of Columbia in August 2019. VASOSTRICT[®] remains the only vasopressin injection product with an NDA approved by the FDA.

Strategy

Endo International plc is a highly focused specialty branded and generics pharmaceutical company that, through its operating subsidiaries, seeks to deliver quality medicines to patients in need through excellence in development, manufacturing and commercialization. Our strategic priorities include reshaping our organization for success, building our portfolio and capabilities for the future and driving margin expansion and, over the longer term, de-levering. Specific areas of management's focus include:

- Branded Pharmaceuticals: Accelerating performance of organic growth drivers in our Specialty Products portfolio and expanding margin in our Established Products portfolio. As further described below under the heading "Select Development Projects," management is also focused on investing in key pipeline life cycle management and other development opportunities, including in the areas of medical therapeutics and medical aesthetics.
- 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 developing or acquiring high-barrier-to-entry, generic injectable products that are difficult to manufacture.
- 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 where physicians play a significant role in choosing the course of therapy and seeking to expand distribution of certain of our products outside of the U.S.

Going forward, our primary focus will be on organic growth. However, we will evaluate and, where appropriate, execute on opportunities to expand through acquisitions of products and companies. There can be no assurance that we will be successful in executing on our strategy.

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, 2019 and 2018 (dollars in thousands):

	2019	2018	% Change 2019 vs. 2018
Total turnover, net	\$ 2,914,364	\$ 2,947,078	(1)%
Cost of sales	1,569,338	1,631,682	(4)%
Gross margin.....	\$ 1,345,026	\$ 1,315,396	2 %
<i>Gross margin percentage</i>	<i>46.2%</i>	<i>44.6%</i>	
Selling, general and administrative	632,420	646,037	(2)%
Research and development.....	130,732	185,826	(30)%
Litigation-related and other contingencies, net	(6,289)	13,809	(146)%
Asset impairment charges	526,082	916,939	(43)%
Acquisition-related and integration items, net.....	(46,098)	21,914	NM
Interest expense, net.....	538,734	521,656	3 %
Gain on extinguishment of debt	(119,828)	—	NM
Other expense (profit), net	16,677	(51,953)	NM
Loss from continuing operations before income tax.....	\$ (327,404)	\$ (938,832)	(65)%

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

Total turnover, net. Turnover from our Sterile Injectables segment, including VASOSTRICT[®] and ADRENALIN[®], our Branded Pharmaceuticals segment’s Specialty Products portfolio, led by XIAPLEX[®], and recent product launches, as further described below, increased during 2019. Turnover from our Branded Pharmaceuticals segment’s Established Products portfolio and both our Generic Pharmaceuticals and International Pharmaceuticals segments decreased during 2019. Our turnover is further disaggregated and described below under the heading “Business Segment Results Review.”

Cost of sales and gross margin percentage. During the years ended December 31, 2019 and 2018, we incurred certain charges that impact the comparability of total Cost of sales, including those related to amortization expense and retention and separation benefits and other cost reduction initiatives, including restructurings. The following table summarizes such amounts (in thousands):

	2019	2018
Amortization of intangible assets (1)	\$ 543,862	\$ 622,339
Retention and separation benefits and other cost reduction initiatives (2)	\$ 5,693	\$ 60,434

(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 2019 was primarily driven by 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 accelerated depreciation charges, employee separation costs, charges to increase excess stock reserves related to restructurings and other cost reduction and restructuring charges. See Note 4. Restructuring for discussion of our material restructuring initiatives.

Reductions to amortization expense and expenses related to retention and separation benefits and other cost reduction initiatives resulted in decreased Cost of sales and increased gross margin percentage. The overall decrease in turnover described above also contributed to the decrease in Cost of sales. Changes in product mix partially offset these items. These changes in mix included both the favorable impact of overall shifts to higher margin Sterile Injectables and Specialty Products from lower margin Generic Pharmaceuticals and Established Products, as well as the unfavorable impact of increased sales of certain lower margin authorized generic products launched since the third quarter of 2018.

Selling, general and administrative expenses. The decrease in 2019 was primarily driven by decreases in long-term incentive compensation costs related primarily to the timing of certain 2018 awards, the impact of certain separations, restructurings and other cost reduction initiatives and a lower branded prescription drug fee. These decreases were partially offset by increased costs related to our continued investment and promotional efforts behind XIAFLEX[®], costs associated with our planned commercial launch of CCH for the treatment of cellulite in the buttocks, a third-quarter 2019 premium associated with an extended reporting period endorsement on an expiring insurance program, increased legal costs related to certain litigation matters and costs related to retention bonuses awarded to certain senior management of the Group in 2019. Our material restructuring initiatives and legal proceedings and other contingent matters are described more fully in Note 4. Restructuring and Note 14. Commitments and Contingencies, respectively.

We expect Selling, general and administrative expense in 2020 to increase compared to 2019 primarily due to increased costs associated with preparing for our planned commercial launch of CCH for the treatment of cellulite in the buttocks, if approved.

R&D expenses. The amount of R&D expense we record in any period varies depending on the nature and stage of development of our R&D programs and can also vary in periods in which we incur significant upfront or milestone charges related to agreements with third parties.

In recent years, our R&D efforts have focused primarily on developing a balanced, diversified portfolio of innovative and clinically differentiated product candidates. We have been progressing and expect to continue to progress our cellulite treatment development program. In early 2020, we announced that we had initiated our XIAFLEX[®] development programs for the treatment of plantar fibromatosis and adhesive capsulitis. We also expect to continue to focus investments in our Sterile Injectables segment, potentially including license and commercialization agreements such as our Nevakar, Inc. agreement, which is further described in Note 11. License and Collaboration Agreements. In addition, we are conducting an open-label Phase 1 pharmacokinetic (PK) study of VASOSTRICT[®] in healthy volunteers, studying plasma clearance with TT genotype versus AA/AT genotype.

In 2019, R&D expense decreased, primarily due to reduced costs associated with our clinical trials of CCH for the treatment of cellulite, the impact of a 2018 upfront payment of \$35.0 million related to the Nevakar, Inc. agreement and the impact of certain separations, restructurings and other cost reduction initiatives. Partially offsetting these decreases was the impact of costs associated with certain post-marketing commitments. Our material restructuring initiatives are described more fully in Note 4. Restructuring.

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 settlement proceeds related to suits filed by our subsidiaries. Our material legal proceedings and other contingent matters are described in more detail in Note 14. Commitments and Contingencies. As further described therein, adjustments to the corresponding liability accruals may be required in the future. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Asset impairment charges. The following table presents the components of our total Asset impairment charges for the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
Goodwill impairment charges	\$ 171,908	\$ 680,000
Other intangible asset impairment charges.....	347,706	230,418
Tangible assets impairment charges	6,468	6,521
Total asset impairment charges	<u>\$ 526,082</u>	<u>\$ 916,939</u>

The factors leading to our material goodwill and intangible asset impairment tests, as well as the results of these tests, are further described in Note 10. Goodwill and Other Intangibles.

Acquisition-related and integration items, net. Acquisition-related and integration items, net in 2019 and 2018 primarily consist of the net (benefit) expense from changes in the fair value of acquisition-related contingent consideration liabilities resulting 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 incurring, and extent to which we could incur, related contingent obligations. See Note 6. Fair Value Measurements for further discussion of our acquisition-related contingent consideration.

Interest expense, net. The components of Interest expense, net for the years ended December 31, 2019 and 2018 are as follows (in thousands):

	2019	2018
Interest expense.....	\$ 558,680	\$ 534,850
Interest income.....	(19,946)	(13,194)
Interest expense, net.....	<u>\$ 538,734</u>	<u>\$ 521,656</u>

The increase in interest expense in 2019 was primarily attributable to changes to LIBOR that impacted our variable-rate debt, increases to the weighted average interest rate applicable to our senior notes and senior secured notes following the March 2019 Refinancing Transactions and interest expense associated with our June 2019 Revolving Credit Facility draw of \$300.0 million. These increases were partially offset by the reductions to the amount of our indebtedness associated with the March 2019 Refinancing Transactions. Refer to Note 13. Debt for further discussion of these transactions. Changes in interest rates could increase our interest expense in the future, which could have material adverse effect on our business, financial condition, results of operations and cash flows.

Interest income varies primarily based on the amounts of our interest-bearing investments, such as money market funds, as well as changes in the corresponding interest rates.

(Gain) loss on extinguishment of debt. The gain on extinguishment of debt recognized in 2019 relates to the March 2019 Refinancing Transactions. Refer to Note 13. Debt for further discussion.

Other expense (profit), net. The components of Other expense (profit), net for the years ended December 31, 2019 and 2018 are as follows (in thousands):

	2019	2018
Net gain on sale of business and other assets.....	\$ (6,367)	\$ (45,155)
Foreign currency loss (gain), net.....	5,247	(3,762)
Net loss from our investments in the equity of other companies.....	2,346	3,444
Other miscellaneous, net.....	15,451	(6,480)
Other expense (profit), net.....	<u>\$ 16,677</u>	<u>\$ (51,953)</u>

For additional information on the components of Other expense (profit), net, refer to Note 18. Other Expense (Profit), Net.

Income tax expense (benefit). The following table displays our Loss from continuing operations before income tax, Income tax expense and Effective tax rate for the years ended December 31, 2019 and 2018 (dollars in thousands):

	2019	2018
Loss from continuing operations before income tax.....	\$ (327,404)	\$ (938,832)
Income tax expense.....	\$ 15,680	\$ 22,935
Effective tax rate.....	(4.8)%	(2.4)%

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 income tax expense in 2019 primarily related to accrued interest on uncertain tax positions. The income tax expense in 2018 primarily related to the establishment of a valuation allowance against certain U.S. deferred tax assets.

We have valuation allowances established against our deferred tax assets in most 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, 2019, it is possible that there could be material reversals, particularly if certain proposed law changes were to be enacted.

The IRS presently is examining certain of our subsidiaries' U.S. income tax returns for fiscal years ended 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 U.S. 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, including the Canada Revenue Agency, are currently examining our non-U.S. tax returns. Additionally, other jurisdictions where we are not currently under audit remain subject to potential future examinations. 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 condition, results of operations and cash flows. 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 the "Principal Risks" section of this document for more information.

For additional information on our income taxes, see Note 19. Income Taxes.

Discontinued operations, net of tax. The operating results of the Group's Astora business, which the Board 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 results of our discontinued operations, net of tax, were losses of \$92.1 million and \$69.7 million in 2019 and 2018, respectively. These amounts consist of Litigation-related and other contingencies, net of \$60.4 million and \$34.0 million, respectively, mesh-related legal defense costs and certain other items. For additional discussion of mesh-related matters, refer to Note 14. Commitments and Contingencies.

Business Segment Results Review

During the first quarter of 2019, the Group changed the names of its reportable segments. This change, which was intended to simplify the segments' names, had no impact on the Group's Consolidated Financial Statements or segment results for any of the periods presented. Refer to Note 5. Segment Results for further details regarding this change, our reportable segments in general and segment adjusted profit from continuing operations before income tax (the measure we use to evaluate segment performance), as well as reconciliations of Total consolidated loss from continuing operations before income tax, which is determined in accordance with U.S. GAAP, to our total segment adjusted profit from continuing operations before income tax.

We refer to segment adjusted profit from continuing operations before income tax, a financial measure not defined by U.S. GAAP, 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 segment adjusted profit from continuing operations before income tax may be useful to investors as we are aware that certain of our significant shareholders utilize segment adjusted profit from continuing operations before income tax to evaluate our financial performance. Finally, segment adjusted profit from continuing operations before income tax is utilized in the calculation of other financial measures not determined in accordance with U.S. GAAP that are used by the Compensation Committee of the Group's Board 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 segment adjusted profit from continuing operations before income tax. Other companies in our industry may define segment adjusted profit from continuing operations before income tax differently than we do. As a result, it may be difficult to use segment 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, segment 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, in Note 5. Segment Results, reconciliations of Total consolidated loss from continuing operations before income tax, which is determined in accordance with U.S. GAAP, to our total segment adjusted profit from continuing operations before income tax.

Turnover, net. The following table displays our turnover by reportable segment for the years ended December 31, 2019 and 2018 (dollars in thousands):

	2019	2018	% Change 2019 vs. 2018
Branded Pharmaceuticals	\$ 855,402	\$ 862,832	(1)%
Sterile Injectables	1,063,131	929,566	14 %
Generic Pharmaceuticals	879,882	1,012,215	(13)%
International Pharmaceuticals (1).....	115,949	142,465	(19)%
Total net turnover from external customers	<u>\$ 2,914,364</u>	<u>\$ 2,947,078</u>	(1)%

(1) Turnover generated by our International Pharmaceuticals segment are primarily attributable to external customers located in Canada.

Branded Pharmaceuticals. The following table displays the significant components of our Branded Pharmaceuticals turnover from external customers for the years ended December 31, 2019 and 2018 (dollars in thousands):

	2019	2018	% Change 2019 vs. 2018
<i>Specialty Products:</i>			
XIAFLEX®	\$ 327,638	\$ 264,638	24 %
SUPPRELIN® LA.....	86,797	81,707	6 %
Other Specialty (1).....	105,241	98,230	7 %
Total Specialty Products.....	<u>\$ 519,676</u>	<u>\$ 444,575</u>	17 %
<i>Established Products:</i>			
PERCOCET®.....	\$ 116,012	\$ 122,901	(6)%
TESTOPEL®.....	55,244	58,377	(5)%
Other Established (2)	164,470	236,979	(31)%
Total Established Products	<u>\$ 335,726</u>	<u>\$ 418,257</u>	(20)%
Total Branded Pharmaceuticals (3)	<u>\$ 855,402</u>	<u>\$ 862,832</u>	(1)%

(1) Products included within Other Specialty are NASCOBAL® Nasal Spray and AVEED®. Beginning with our first-quarter 2019 reporting, TESTOPEL®, which was previously included in Other Specialty, has been reclassified and is now included in the Established Products portfolio for all periods presented.

(2) Products included within Other Established include, but are not limited to, LIDODERM®, EDEX® and VOLTAREN® Gel.

(3) Individual products presented above represent the top two performing products in each product category for the year ended December 31, 2019 and/or any product having turnover in excess of \$100 million during any of the years ended December 31, 2019 or 2018 or \$25 million during any quarterly period in 2019 or 2018.

Specialty Products

The increase in XIAFLEX® in 2019 was primarily attributable to demand growth driven by the continued investment and promotional efforts behind XIAFLEX®, as well as price.

The increase in SUPPRELIN® LA in 2019 was primarily attributable to increases in both volume and price.

The increase in Other Specialty Products in 2019 was primarily attributable to increased volume of both NASCOBAL[®] Nasal Spray and AVEED[®].

Established Products

The decrease in PERCOCET[®] in 2019 was primarily attributable to decreased volume, partially offset by increased price.

The decrease in TESTOPEL[®] in 2019 was primarily attributable to both price and volume decreases.

The decrease in Other Established Products in 2019 was primarily attributable to volume decreases as a result of ongoing competitive pressures.

Sterile Injectables. The following table displays the significant components of our Sterile Injectables turnover from external customers for the years ended December 31, 2019 and 2018 (dollars in thousands):

	2019	2018	% Change 2019 vs. 2018
VASOSTRICT [®]	\$ 531,737	\$ 453,767	17 %
ADRENALIN [®]	179,295	143,489	25 %
Ertapenem for injection.....	104,679	57,668	82 %
APLISOL [®]	61,826	64,913	(5)%
Other Sterile Injectables (1)	185,594	209,729	(12)%
Total Sterile Injectables (2).....	<u>\$ 1,063,131</u>	<u>\$ 929,566</u>	14 %

(1) Products included within Other Sterile Injectables include ephedrine sulfate injection, treprostinil for injection and others.

(2) Individual products presented above represent the top two performing products within the Sterile Injectables segment for the year ended December 31, 2019 and/or any product having turnover in excess of \$100 million during any of the years ended December 31, 2019 or 2018 or \$25 million during any quarterly period in 2019 or 2018.

The increase in VASOSTRICT[®] in 2019 was primarily attributable to changes in price, volume and mix of business. As of December 31, 2019, we have six patents for VASOSTRICT[®] listed in the Orange Book and 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. As further discussed in Note 14. Commitments and Contingencies under the heading “VASOSTRICT[®] Related Matters,” we are aware of certain competitive actions taken by other pharmaceutical companies related to VASOSTRICT[®]. 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 competing versions of VASOSTRICT[®] could result in reductions to our market share, turnover, profitability and cash flows.

The increase in ADRENALIN[®] in 2019 was primarily attributable to increased price and volume.

Ertapenem for injection, the authorized generic of Invanz[®], launched during the third quarter of 2018. The increase in 2019 was driven by the timing of this product’s launch.

The decrease in APLISOL[®] in 2019 was primarily attributable to decreased volume, partially offset by increased price.

The decrease in Other Sterile Injectables in 2019 was primarily driven by certain competitive pressures impacting multiple products in this portfolio.

Generic Pharmaceuticals. The decrease for the Generic Pharmaceuticals segment in 2019 was primarily attributable to continued competitive pressure on commoditized generic products. Partially offsetting the decrease were the impacts of certain recent product launches including, among others, the second-quarter 2019 launch of albuterol sulfate HFA inhalation aerosol, the authorized generic of Proventil[®], and the third-quarter 2018 launch of colchicine tablets.

International Pharmaceuticals. The decrease for the International Pharmaceuticals segment in 2019 was primarily attributable to competitive pressures in certain international markets and the impact of certain product discontinuation activities.

Segment adjusted profit from continuing operations before income tax. The following table displays our segment adjusted profit from continuing operations before income tax by reportable segment for the years ended December 31, 2019 and 2018 (dollars in thousands):

	2019	2018	% Change 2019 vs. 2018
Branded Pharmaceuticals	\$ 362,711	\$ 368,790	(2)%
Sterile Injectables	\$ 780,799	\$ 695,363	12 %
Generic Pharmaceuticals	\$ 158,400	\$ 317,892	(50)%
International Pharmaceuticals	\$ 44,758	\$ 59,094	(24)%

Branded Pharmaceuticals. The decrease in 2019 was primarily attributable to increased costs related to our continued investment and promotional efforts behind XIAFLEX[®] and costs associated with our planned commercial launch of CCH for the treatment of cellulite in the buttocks. This was offset by increased gross margins resulting from changes in product mix and lower R&D expense resulting from reduced costs associated with our clinical trials of CCH, partially offset by increased costs associated with certain post-marketing commitments.

Sterile Injectables. The increase in 2019 was primarily driven by increased turnover and gross margins resulting from strong performance across several products in this segment.

Generic Pharmaceuticals. The decrease in 2019 was primarily attributable to decreased turnover as described above and the resulting reduction to gross margin. Additionally, gross margin was negatively impacted by changes in product mix resulting from increased sales of certain lower margin authorized generic products. These decreases were partially offset by reduced expenses including the impact of certain restructuring and other cost saving initiatives and a lower branded prescription drug fee. Our material restructuring initiatives are described in Note 4. Restructuring.

International Pharmaceuticals. The decrease in 2019 was primarily attributable to decreased turnover as described above and the resulting reduction to gross margin.

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, debt service payments and litigation-related matters, including vaginal mesh liability payments. The Group's working capital was \$1,138.4 million at December 31, 2019 compared to working capital of \$393.1 million at December 31, 2018. The amounts at December 31, 2019 and December 31, 2018 include restricted cash at bank and on-hand of \$242.8 million and \$299.7 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.

Cash at bank and on-hand, which primarily consisted of bank deposits and money market accounts, totaled \$1,454.5 million at December 31, 2019 compared to \$1,149.1 million at December 31, 2018. While we currently expect our operating cash flows, together with our cash, cash equivalents, restricted cash and restricted cash equivalents, to be sufficient to cover our principal liquidity requirements over the next year, the extent to which COVID-19 could impact our business, financial condition, results of operations and cash flows in the short- and medium-term cannot be predicted with certainty, but such impact could be material. Although we did not experience significant disruptions to our business during the first quarter of 2020 from COVID-19, we have since experienced and expect that we, and our industry as a whole, will continue to experience a greater impact going forward. To the extent COVID-19 has resulted in any increase to our Cash and cash equivalents, including as a result of any increase in revenues as described above, such increase could be temporary.

Additionally, 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 costs in connection with our business operations, our ongoing and future legal proceedings, governmental investigations and other contingent liabilities, including potential costs related to settlements and judgments, as well as legal defense costs, and the implementation of our COVID-19 related policies and procedures. 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 have a material adverse effect on our business, financial condition, results of operations and cash flows and require us to seek additional sources of liquidity and capital resources as described below. For information regarding the impact of COVID-19 on the Group, including on our liquidity and capital resources, please refer to “Principal Risks” in this report.

To the extent our operating cash flows, together with our cash at bank and in-hand, restricted cash at bank and in-hand, become insufficient to cover our liquidity and capital requirements, including funds for any future acquisitions and other corporate transactions, we may be required to seek third-party financing, including additional draws on our Revolving Credit Facility or additional credit facilities, and/or engage in one or more capital markets transactions. The COVID-19 pandemic has resulted in significant disruptions to and volatility in the local, national and global financial markets and there can be no assurance that we would be able to obtain any required financing on a timely basis or at all. Further, lenders and other financial institutions could require us to agree to more restrictive covenants, grant liens on our assets as collateral (resulting in an increase in our total outstanding secured indebtedness) and/or accept other terms that are not commercially beneficial to us in order to obtain financing, as a result of the actual or perceived impact that financial institutions believe the pandemic will have on our business. Such terms could further restrict our operations and exacerbate any impact on our results of operations and liquidity that may result from COVID-19.

We may also, from time to time, seek to enter into certain transactions to reduce 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 or other debt (including exchanges of unsecured debt for secured debt), to issue equity (including convertible securities) or to repurchase, redeem, exchange or refinance our existing indebtedness (including the Credit Agreement), as well as our outstanding senior notes. Any of these transactions could impact our liquidity or results of operations. Our ability to obtain any third-party financing needed for such transactions is subject to the same uncertainties relating to the disruptions to and volatility in the financial markets described above. Further, the terms of any such transactions, including the amount of any exchange consideration and terms of any refinanced debt, could also be less favorable than we have been able to obtain in the past, including a requirement that we grant liens on our assets as collateral (resulting in an increase in our total outstanding secured indebtedness), as a result of changing market conditions and investment interest from the pandemic and its impact on our business and the financial markets.

We consider the undistributed earnings from the majority of our subsidiaries as of December 31, 2019 to be indefinitely reinvested outside of Ireland and, accordingly, neither income tax nor withholding taxes have been provided thereon. As of December 31, 2019, indefinitely reinvested earnings were approximately \$1,092.0 million. We do not anticipate incurring tax in deploying funds to satisfy liquidity needs arising in the ordinary course of business.

Indebtedness. The Group and/or certain of its subsidiaries are party to the Credit Agreement governing the Credit Facilities (as defined in Note 13. Debt) and the indentures governing our various senior secured and senior unsecured notes. As of December 31, 2019, approximately \$3.3 billion was outstanding under the Term Loan Facility, approximately \$0.3 billion was outstanding under the Revolving Credit Facility and approximately \$4.8 billion was outstanding under the senior secured and senior unsecured notes.

After giving effect to previous borrowings and issued and outstanding letters of credit, approximately \$0.7 billion of remaining credit was available under the Revolving Credit Facility at December 31, 2019. The Group’s outstanding debt agreements contain a number of restrictive covenants, including certain limitations on the Group’s ability to incur additional indebtedness.

The Credit Agreement and the indentures governing our various notes contains certain covenants. As of December 31, 2019 and December 31, 2018, the Group was in compliance with all such covenants. In addition, after each fiscal year-end, 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, 2019.

Refer to Note 13. Debt for additional information about our indebtedness, including information about covenants, maturities, interest rates, security and priority.

Credit ratings. The Group's corporate credit ratings assigned by Moody's Investors Service and Standard & Poor's are B3 with a stable outlook and B with a negative outlook, respectively. No report of any rating agency is being incorporated by reference herein.

Working capital. The components of our working capital and our liquidity at December 31, 2019 and December 31, 2018 are below (dollars in thousands):

	December 31, 2019	December 31, 2018
Total current assets	\$ 2,586,218	\$ 2,343,150
Less: total current liabilities	1,447,789	1,950,096
Working capital	<u>\$ 1,138,429</u>	<u>\$ 393,054</u>
Current ratio (total current assets divided by total current liabilities)	1.8:1	1.2:1

Net working capital increased by \$745.4 million from December 31, 2018 to December 31, 2019. This increase primarily reflects the increase to cash of \$300.0 million as a result of the June 2019 borrowing under the Revolving Credit Facility and the favorable impact to net current assets resulting from operations during the year ended December 31, 2019. This activity was partially offset by certain items that occurred during the year ended December 31, 2019 including, but not limited to, the impact of adopting ASC 842, which resulted in a net decrease to working capital of approximately \$10.7 million, purchases of tangible assets, excluding capitalized interest, of \$63.9 million and our incurrence of financing fees in connection with the March 2019 Refinancing Transactions.

The following table summarizes our Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
Net cash flow provided by (used in):		
Operating activities	\$ 98,052	\$ 267,270
Investing activities	(60,198)	(17,900)
Financing activities	204,601	(81,572)
Effect of foreign exchange rate	1,096	(1,975)
Net increase in cash at bank and on-hand and restricted cash at bank and on-hand	<u>\$ 243,551</u>	<u>\$ 165,823</u>

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, MCOs, government agencies, collaborative partners and employees, as well as tax payments and refunds in the ordinary course of business.

The \$169.2 million decrease in Net cash provided by operating activities in 2019 compared to the prior year was primarily due to our results of operations as described above and the timing of cash collections and cash payments related to our operations. Cash paid for interest increased by \$44.5 million as a result of the timing and amounts of interest payments related to our indebtedness. Additionally, we increased stock levels during the year ended December 31, 2019 in advance of certain recent and planned future product launches, which utilized cash. We expect that payments for previously accrued legal matters, which are further discussed in Note 14. Commitments and Contingencies will continue to impact our Net cash provided by operating activities in future periods.

Investing activities. The \$42.3 million increase in Net cash used in investing activities in 2019 compared to the prior year reflects a decrease in Proceeds from sale of business and other assets, net of \$63.8 million, offset in part by a decrease in Purchases of tangible assets, excluding capitalized interest of \$19.5 million.

Financing activities. During 2019, Net cash provided by financing activities related primarily to the \$300.0 million June 2019 borrowing under the Revolving Credit Facility. The proceeds from this transaction were offset by Repayments of term loans of \$34.2 million, Payments for contingent consideration of \$16.8 million, Payments of tax withholding for restricted shares of \$10.2 million, Repayments of other indebtedness of \$9.2 million and the net effect of the March 2019 Refinancing Transactions, which resulted in Proceeds from issuance of notes, net of \$1,483.1 million, cash used for Repayments of notes totaling \$1,500.0 million and Payments for debt issuance and extinguishment costs of \$6.4 million.

During 2018, Net cash used in financing activities related primarily to Payments for contingent consideration of \$37.8 million, Repayments of term loans of \$34.2 million and Payments of tax withholding for restricted shares of \$5.4 million.

R&D. 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 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 compound, product or indication under development will receive regulatory approval in a timely manner or at all or that such compound, 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 a material 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. 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 Sheet. In addition, we may be required to make sales-based royalty or similar payments under certain arrangements.

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 14. Commitments and Contingencies.

Contractual Obligations. The following table lists our enforceable and legally binding noncancelable obligations as of December 31, 2019.

	Payment Due by Period (in thousands)						
	Total	2020	2021	2022	2023	2024	Thereafter
Long-term debt obligations (1)	\$ 8,470,678	\$ 34,150	\$ 34,150	\$ 247,723	\$ 1,684,430	\$ 3,770,225	\$ 2,700,000
Interest expense (2)	2,542,549	525,976	523,927	510,591	457,330	265,400	259,325
Finance lease obligations (3)	52,216	7,446	7,593	7,743	7,897	8,054	13,483
Operating lease obligations (3)	70,578	14,103	13,262	12,688	10,017	5,176	15,332
Purchase obligations (4)	37,471	20,319	11,927	818	941	632	2,834
Mesh-related product liability settlements (5)...	54,769	54,769	—	—	—	—	—
Other obligations and commitments (6)	1,602	1,602	—	—	—	—	—
Total (7).....	\$ 11,229,863	\$ 658,365	\$ 590,859	\$ 779,563	\$ 2,160,615	\$ 4,049,487	\$ 2,990,974

- (1) Includes minimum cash payments related to principal associated with our indebtedness as of December 31, 2019. A discussion of such indebtedness is included above under the caption “Indebtedness.” The amounts in this table do not reflect any potential early or accelerated principal payments such as the potential payments described in Note 13. Debt.
- (2) These amounts represent future cash interest payments related to our indebtedness as of December 31, 2019 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, 2019, plus the specified margin in the associated debt agreements for each period presented.
- (3) Refer to Note 8. Leases for additional information about our leases. We have entered into agreements to sublease certain properties. Most significantly, we sublease 140,000 square feet of our Malvern, Pennsylvania facility and substantially all of our Chesterbrook, Pennsylvania facility. As of December 31, 2019, we expect to receive approximately \$24.7 million in future minimum rental payments over the remaining terms of the Malvern and Chesterbrook subleases from 2020 to 2024. Amounts of expected sublease profit are not reflected in the table above.
- (4) Purchase obligations are enforceable and legally binding obligations for purchases of goods and services, including minimum stock contracts.
- (5) 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 14. Commitments and Contingencies.
- (6) Other obligations and commitments relate to any agreements to purchase third-party assets, products and services and other minimum royalty obligations.
- (7) Total generally does not include contractual obligations already included in current liabilities on our Consolidated Balance Sheet, except for amounts related to the current portion of long-term debt, accrued interest, current 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, 2019, 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 19. 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, if any. 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, the impact of financing transactions, 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. The impact of COVID-19 may heighten these fluctuations in our operating results.

Additionally, the current economic crisis and rising unemployment rates resulting from COVID-19 have significantly reduced individual disposable income and depressed consumer confidence, which could limit the ability of some consumers to purchase certain pharmaceutical products and reduce consumer spend on certain medical procedures in both the short- and medium-term. Additionally, as part of the measures to address COVID-19, certain healthcare providers are not currently performing various medical procedures.

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 group 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 loss of \$5.2 million in 2019 and a net gain of \$3.8 million in 2018.

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 Credit Facilities. At December 31, 2019 and 2018, the aggregate principal amounts of such variable-rate indebtedness were \$3,629.6 million and \$3,363.8 million, respectively. Borrowings under the Credit Facilities may from time to time bear interest at variable rates, as further described in Note 13. Debt, in certain cases subject to a floor. At December 31, 2019 and 2018, a hypothetical 1% increase in the applicable rate over the floor would have resulted in \$36.3 million and \$33.6 million, respectively, of incremental interest expense (representing the annual rate of expense) related to our variable-rate debt borrowings.

To the extent that we utilize additional amounts under the Revolving Credit Facility or otherwise increase the amount of our variable-rate indebtedness, we will be exposed to additional interest rate risk.

As of December 31, 2019 and 2018, we had no other assets or liabilities with significant interest rate sensitivity.

Foreign Currency Exchange Rate 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 and foreign currency assets in relation to same-currency liabilities. The Group is also exposed to 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. Such remeasurement adjustments could have a material adverse effect on the Group's financial position and 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 expense (profit), net in the Consolidated Profit and Loss Account. Refer to Note 18. Other Expense (Profit), Net for the amount of Foreign currency loss (gain), net.

Based on the Group's significant foreign currency denominated intercompany loans, we separately considered the hypothetical impact of a 10% change in the underlying currencies of our foreign currency denominated intercompany loans, relative to the U.S. dollar, at December 31, 2019 and 2018. A 10% change at December 31, 2019 would have resulted in approximately \$11 million in incremental foreign currency losses on such date. A 10% change at December 31, 2018 would have resulted in approximately \$9 million in incremental foreign currency losses on such date.

Principal Risks

Widespread health problems, including the recent global coronavirus, could materially and adversely affect our business.

Public health outbreaks, epidemics or pandemics, such as the coronavirus, could materially and adversely impact our business. For example, in December 2019, COVID-19 was reported to have surfaced in Wuhan, China. In March 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. COVID-19 has resulted in global business and economic disruption and extreme volatility in the financial markets as many jurisdictions have placed restrictions on travel and non-essential business operations and implemented social distancing, shelter-in-place, quarantine and other similar measures for their residents to contain the spread of the virus. In response to these public health directives and orders, we have implemented alternative working practices and mandatory work-from-home requirements for appropriate employees, as well as social distancing, modified schedules, shift rotation and other similar policies at our manufacturing facilities, and have transitioned to a "virtual" engagement model to continue supporting healthcare professionals, patient care and access to medicines. We have also suspended international and domestic travel. The effects of COVID-19, including these public health directives and orders and our policies, have had an impact on our business and may in the future materially disrupt our business, including our manufacturing and supply chain operations by significantly reducing our output, negatively impact our productivity and delay our product development programs.

The global pandemic may have significant impacts on third-party arrangements, including those with our manufacturing, supply chain and distribution partners, information technology and other vendors and other service providers and business partners. For example, there may be significant disruptions in the ability of any or all of these third-party providers to meet their obligations to us on a timely basis, or at all, which may be caused by their own financial or operational difficulties, including any closures of their facilities pursuant to a governmental order or otherwise. As a result of these disruptions and other factors, including changes in our workforce availability and increased demand for certain of our critical care products during this pandemic, our ability to meet our obligations to third-party distribution partners may be negatively impacted. As a result, we have recently delivered, and in the future we or our third-party providers may deliver, notices of the occurrence of a *force majeure* or similar event under certain of our third-party contracts, which could result in prolonged commercial disputes and ultimately legal proceedings to enforce contractual performance and/or recover losses. Any such occurrences could result in significant management distraction and use of resources and, in the event of an adverse judgment, could result in significant cash payments. Further, the publicity of any such dispute could harm our reputation and make the negotiation of any replacement contracts more difficult and costly, thereby prolonging the effects of any resulting disruption in our operations. Such disruptions could be acute with respect to certain of our raw material suppliers where we may not have readily accessible alternatives or alternatives may take longer to source than usual. While we attempt, when possible, to mitigate our raw material supply risks through stock management and alternative sourcing strategies, some raw materials are only available from one source. Any of these disruptions could harm our ability to meet consumer demand, including any increase in demand for any of our products, including our critical care products used during a pandemic.

We have experienced, and may continue to experience, changes in customer demand as the COVID-19 pandemic evolves. The current economic crisis and rising unemployment rates resulting from COVID-19 have the potential to significantly reduce individual disposable income and depress consumer confidence, which could limit the ability of some consumers to purchase certain pharmaceutical products and reduce consumer spend on certain medical procedures in both the short- and medium-term. Additionally, as part of the measures to address COVID-19, certain healthcare providers are not currently performing various medical procedures, including those that use certain of our products. For example, during the last two weeks of the first quarter of 2020, we experienced decreased demand for certain products that are physician administered, including XIAFLEX® and SUPPRELIN® LA. Furthermore, we are unable to predict the impact that COVID-19 may have going forward on the business, results of operations or financial position of any of our major customers, which could impact each customer to varying degrees and at different times and could ultimately impact our own financial performance. Certain of our competitors may also be better equipped to weather the impact of COVID-19 both domestically and abroad and better able to address changes in customer demand.

Additionally, our product development programs may be adversely affected by the global pandemic and the prioritization of production during this pandemic. The public health directives in response to COVID-19 requiring social distancing and restricting non-essential business operations have in certain cases caused and may continue to cause delays, increased costs and additional challenges in our product development programs, including obtaining adequate patient enrollment and successfully bringing product candidates to market. In addition, we may face additional challenges receiving regulatory approvals as previously scheduled dates or anticipated deadlines for action by the FDA on our applications and products in development, including dates scheduled for 2020, could be subject to delays beyond our control as regulators such as the FDA focus on COVID-19. For example, as a result of COVID-19 and its impact on medical aesthetics physician office closures and consumer spending, we are planning on changing the anticipated product launch of CCH for the treatment of cellulite in the buttocks, if approved, to 2021. In addition, we have assessed and expect to continue to assess the timeline for commercialization of other products.

To the extent our operating cash flows, together with our cash, cash equivalents, restricted cash and restricted cash equivalents, become insufficient to cover our liquidity and capital requirements, including funds for any future acquisitions and other corporate transactions, we may be required to seek third-party financing, including additional draws on our Revolving Credit Facility or additional credit facilities, and/or engage in one or more capital markets transactions. The COVID-19 pandemic has resulted in significant disruptions to and volatility in the local, national and global financial markets and there can be no assurance that we would be able to obtain any required financing on a timely basis or at all. Further, lenders and other financial institutions could require us to agree to more restrictive covenants, grant liens on our assets as collateral (resulting in an increase in our total outstanding secured indebtedness) and/or accept other terms that are not commercially beneficial to us in order to obtain financing, as a result of the actual or perceived impact that financial institutions believe the pandemic will have on our business. Such terms could further restrict our operations and exacerbate any impact on our results of operations and liquidity that may result from COVID-19. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our ordinary shares.

Additionally, COVID-19 could increase the magnitude of many of the other risks described herein and have other adverse effects on our operations that we are not currently able to predict. For example, the global economic disruptions and volatility in the financial markets could further depress our ability to obtain or renew insurance on satisfactory terms or at all. Additionally, we may also be required to delay or limit our internal strategies in the short- and medium-term by, for example, redirecting significant resources and management attention away from implementing our strategic priorities or executing opportunistic corporate development transactions.

The magnitude of the effect of COVID-19 on our business will depend, in part, on the length and severity of the restrictions (including the effects of recently announced “re-opening” plans following a recent slowdown of the virus infection rate in certain countries and localities) and other limitations on our ability to conduct our business in the ordinary course. The longer the pandemic continues or resurges, the more severe the impacts described above will be on both our domestic and international business. The extent, length and consequences of the pandemic are uncertain and impossible to predict, but could be material. COVID-19 and other similar outbreaks, epidemics or pandemics could have a material adverse effect on our business, financial condition, results of operations and cash flows and could cause significant volatility in the trading prices of our securities.

We operate in a highly competitive industry.

The pharmaceutical industry is intensely competitive and we face competition in both our U.S. and international branded and generic pharmaceutical business. Competitive factors include, without limitation, product development, technological innovation, safety, efficacy, commercialization, marketing, promotion, product quality, price, cost-effectiveness, reputation, service, patient convenience and access to scientific and technical information. Many of our competitors have, and future competitors 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 include market consolidation, which may further concentrate financial, technical and market strength and increase competitive pressure in the industry. It is possible that our competitors may make greater R&D investments and have more efficient or superior processes and systems and more experience in the development of new products that permit them to respond more quickly to new or emerging technologies and changes in customer demand 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, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Many of our branded products do not currently compete with on-market generic products but are likely to face generic competition in the future. While the entrance of generic competitors could occur at any time and cannot be predicted with certainty, generic competition often follows shortly after the loss of patent protection. See “Patents, Trademarks, Licenses and Proprietary Property” for additional information. Similarly, generic products we currently sell with generic exclusivity could in the future be subject to competition from other generic competitors. Some of our other products, including both branded and generic products, already face generic competition. For these products, we face the risk of additional generic competitors entering the market. Manufacturers of generic products typically invest far less in R&D than research-based companies. Additionally, generic competitors, including Asian or other overseas generic competitors, may be able to produce products at costs lower than us. For these reasons, competitors may be able to price their products lower than we can, and such differences could be material. Due to lower prices, generic versions, where available, may be substituted by pharmacies or required in preference to branded versions under third-party reimbursement programs. As a result, generic competition could have a material adverse effect on our business, financial condition, results of operations and cash flows. Legislation encouraging early and rapid approval of generic drugs could also increase the degree of generic competition we face. See the principal risk “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” for more information.

In addition, our generics business faces competition from brand-name pharmaceutical companies, which have taken and may continue to take aggressive steps to thwart or delay competition from generic equivalents of their brand-name products, including bringing litigation alleging patent infringement or other violations 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 delay or cease the manufacture and sale of such generic product. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our sales may also suffer as a result of changes in consumer demand for our products, including as a result of fluctuations in consumer buying patterns, changes in market conditions or actions taken by our competitors, including the introduction of new products or price reductions for existing products. Any of these factors could have a material adverse effect on our business, financial condition, results of operations 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.

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[®], ADRENALIN[®] 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 turnover from LIDODERM[®] have been negatively affected by multiple competing generic versions of LIDODERM[®]. We anticipate that this turnover could decrease further should one or more additional generic versions of LIDODERM[®] launch.

Additionally, in early 2019, we received notice from a competing pharmaceutical company that manufactures one of our products of its intent to seek approval to launch a competing OTC version of such product. We cannot predict whether this, or any other manufacturer, will take similar actions with respect to other products. Any launch of competing OTC versions of any of our products could decrease the turnover of such products, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our practice is to vigorously defend and pursue all available legal and regulatory avenues in defense of the intellectual property rights protecting our products. Despite our efforts, 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 or data exclusivity rights expire or become otherwise unenforceable, our competitors could ultimately launch generic, biosimilar, OTC or other competing versions of our products. Upon the loss or expiration of patent protection for one of our products, or upon the "at-risk" launch (despite pending patent infringement litigation against the generic product) by a generic manufacturer of a generic version of one of our patented products, our sales and turnover of the affected products would likely decline rapidly and materially, which 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, financial condition, results of operations and cash flows.

In the case of VASOSTRICT[®], beginning in April 2018, Par Sterile Products, LLC (PSP LLC) and Par Pharmaceutical, Inc. (PPI) received notice letters from Eagle Pharmaceuticals, Inc. (Eagle), Sandoz, Inc., Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals, LLC, American Regent and Fresenius advising of the filing by such companies of ANDAs for generic versions of VASOSTRICT[®] (vasopressin IV solution (infusion)). The Paragraph IV notices refer to patents that we have 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. Beginning in May 2018, PPI, PSP LLC and Endo Par Innovation Company, LLC (EPIC) filed lawsuits against the companies in the U.S. District Court for the District of Delaware and New Jersey within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative framework. We intend to pursue all available legal, business and regulatory avenues in defense of VASOSTRICT[®], including enforcement of our intellectual property rights. However, there can be no assurance that we will be successful. If a generic version of VASOSTRICT[®] were introduced to the market, our turnover 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, financial condition, results of operations 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 14. Commitments and Contingencies.

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 through the use of other means. We cannot determine what effect section 610 of the FCAA 2020 may have on manufacturers developing generic, OTC or other competing versions of our products.

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

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. While we have successfully challenged an FDA interim policy that would have permitted the compounding of vasopressin, the active ingredient in VASOSTRICT[®], the introduction of compounded versions of our products by pharmacies or outsourcing facilities could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

Our financial results depend, to a significant extent, upon our ability, and the ability of our partners, to identify, develop, obtain regulatory approval for, launch and commercialize a pipeline of commercially successful branded and generic products, including first-to-file or first-to-market opportunities. Due to the significant competition we face and the importance of being the first (or one of the first) to market, no assurances can be given that we will be able to develop, introduce and maintain commercially successful products in the future. For example, in the case of colchicine tablets, the authorized generic of Takeda's Colcrys[®], we could face competition from Mylan and other manufacturers. In November 2019, Mylan launched its generic version of Colcrys[®] but agreed to temporarily suspend its sales pending the outcome of preliminary injunction proceedings in the litigation by Takeda against Mylan. If Mylan or other manufacturers enter the market, our turnover from colchicine tablets could decrease significantly, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Identifying and developing additional product candidates are prone to risks of failure inherent in product development. We conduct R&D to enable us to manufacture and market pharmaceutical products in accordance with specific government regulations. Much of our product 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 products are significantly greater than those expenses associated with generic products. Should we expand our R&D efforts, our research expenses are likely to increase. Because of the inherent risk associated with R&D efforts in the healthcare industry, particularly with respect to new products, our R&D expenditures may not result in the successful regulatory approval and introduction of new 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 R&D costs to develop a particular product and there is a significant risk that the funds we invest in R&D 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 process of developing and obtaining regulatory approvals for new products is time-consuming, costly and inherently unpredictable. Even if we are able to identify and develop additional product candidates, we may fail to obtain exclusive marketing rights, such as the 180-day ANDA first-filer marketing exclusivity period provided for in the Hatch-Waxman amendments to the FDCA or the 180-day exclusivity for competitive generic therapies (CGTs) established by the FDA Reauthorization Act of 2017, for such product candidates. Even if we were to secure such exclusivities, risks associated with securing timely approval, as well as risks of unfavorable litigation dispositions, put such exclusivities at risk of being forfeited. The approval of our ANDAs may also be stayed by the FDA for up to 30 months if such ANDAs become the subject of patent litigation. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other ANDA applicants or with authorized generics that are not prohibited from sale during the 180-day marketing exclusivity period. Our turnover have historically included sales of generic products with limited competition resulting from marketing exclusivity or other factors, and the failure to timely and effectively file any NDA, ANDA, BLA or Supplemental Biologics License Application (sBLA) with the FDA or similar filings with other regulatory agencies, or to partner with parties that have obtained marketing exclusivity, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

- 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 competitors' products or against our products;
- the cost of our products 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 or their products;
- the advent of new and innovative alternative products;
- any unforeseen issues or adverse developments in connection with our products and any resulting litigation, regulatory scrutiny and/or harm to our reputation; and
- other risks that may be out of our control, including the decision by a collaboration partner to make substantial changes to a product's formulation or design, or a collaboration partner refusing to perform its obligations under our collaboration agreement, which may cause delays and additional costs in developing and marketing a product.

We have been and expect to continue to be the subject of lawsuits, product liability claims, other significant legal proceedings, governmental investigations or product recalls, any of which could have a material adverse effect on our company.

Our business exposes us to significant potential risks from lawsuits, product liability claims, other significant legal proceedings, governmental investigations and/or product recalls, including, but not limited to, matters associated with the testing, manufacturing, marketing, sale and use of our products. Some plaintiffs have received substantial damage awards against or entered into significant settlements with healthcare companies based upon various legal theories, including without limitation, claims for injuries allegedly caused by the use of their products. We have been, and expect to continue to be subject to various lawsuits, product liability claims, other significant legal proceedings and governmental investigations or product recalls, any of which could have a material adverse effect on our company or cause us to take significant corporate transactions and remedial measures.

For example, we, along with other manufacturers of prescription opioid medications, as well as distributors and other sellers of such medications, are the subject of lawsuits and have received subpoenas and other requests for information from various federal, state and local government agencies regarding the sale, marketing and/or distribution of prescription opioid medications. Numerous claims against opioid manufacturers, including us, have been and may continue to be filed by or on behalf of various plaintiffs, including 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 14. Commitments and Contingencies for more information. In these cases, plaintiffs have sought 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 these cases, settlement demands and discussions often seek significant monetary and other remedies, and we have received some settlement offers that are on terms that we do not consider reasonable under the circumstances or indicative of the merits or potential outcome of any court proceeding with respect to the underlying claims. Additionally, while we have made the decision to settle some claims, there can be no assurance that settlement opportunities will continue to be available generally, or be consistent with our historic experience. We may not be able to settle all of our opioid claims successfully, and as a result, we may go to trial in certain of these cases. Awards against and settlements by us or our competitors could also incentivize parties to bring additional claims against us. In addition to the risks of direct expenditures for defense costs, settlements and/or judgments in connection with these claims, proceedings and investigations, there is a possibility of loss of revenues, injunctions and disruption of business. Additionally, we have, and may continue to receive, claims or requests for indemnification from certain of our customers. 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. Certain other manufacturers of prescription opioid medications have publicly commenced, or announced their intention to commence, cases to seek the protections under Chapter 11 of the Bankruptcy Code to address the claims being asserted against such manufacturers in these opioid lawsuits.

Our current and former products may cause or 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 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 POP and SUI. The 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 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 Group. See Note 14. Commitments and Contingencies 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 Group to legal proceedings, penalties, fines and/or 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 and settlements obtained in litigation against us or other pharmaceutical companies as an advertising tool. For these or other reasons, any product liability or other 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 the 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 other litigation in which we are not a defendant could have a negative impact on pending litigation where we are a defendant.

In addition, in certain circumstances, such as in the case of products that do not meet approved specifications or which subsequent data demonstrate 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 or other products, including without limitation law enforcement concerns over diversion or marketing practices, regulatory efforts to combat abuse, and litigation could result in costs to our business" for more information.

If we are found liable in any lawsuits, including product liability claims or actions related to our sales, marketing or pricing practices or the sale, marketing and/or distribution of prescription opioid medications, or if we are subject to governmental investigations or product recalls, it could result in the imposition of material damages, including punitive damages, fines, reputational harm, civil lawsuits, 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. Any judgments, claims, settlements and related costs could be well in excess of any applicable insurance. As a result, we may experience significant negative impacts on our operations or financial position. To satisfy judgments or settlements, we also may need to seek financing or bonding, which may not be available on terms acceptable to us, or at all, when required, particularly given the extreme volatility in the capital markets. Judgments also could cause defaults under our debt agreements and/or restrictions on product use or business practices and we could incur losses as a result. Any of the risks above could have a material adverse effect on our business, financial condition, results of operations and cash flows and could be further exacerbated by the impact of COVID-19.

The occurrence or possibility of any such result may cause us to engage in a strategic review that ultimately results in us pursuing one or more significant corporate transactions or remedial measures. Any such actions or measures could include reorganization or restructuring activities, asset sales or other divestitures, cost-saving initiatives or other corporate realignments, seeking strategic partnerships and exiting certain product or geographic markets. See the principal risk "Our ability to fund our operations, maintain adequate liquidity and meet our financing obligations is reliant on our operations, which are subject to significant risks and uncertainties" for more information. Any of such actions 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, or that they will result in their intended benefits.

See Note 14. Commitments and Contingencies included in this report for further discussion of the foregoing and other material legal proceedings.

We may not have and may be unable to obtain or maintain insurance adequate to cover potential liabilities.

We may not have and may be unable to obtain or maintain in the future 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.

Our ability to fund our operations, maintain adequate 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 described in this “Principal Risks” section, including those related to generic competition and legal challenges that could impact our key products, including VASOSTRICT[®], outstanding and future legal proceedings and governmental investigations, including those related to our sale, marketing and/or distribution of prescription opioid medications, and others. 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 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 (which could increase our cost of capital) 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;
- limiting our ability to incur additional borrowings under the covenants in our then-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; and/or
- otherwise causing us to be unable to fund our operations and liquidity needs, such as future capital expenditures and payment of our indebtedness.

The occurrence or possibility of any such result may cause us to engage in a strategic review that ultimately results in us pursuing one or more significant corporate transactions or remedial measures. Any such actions or measures could include reorganization or restructuring activities, asset sales or other divestitures, cost-saving initiatives or other corporate realignments, seeking strategic partnerships and exiting certain product or geographic markets. Additionally, we may need to refinance all or part of our then-existing indebtedness, reduce or delay capital expenditures or seek to raise additional capital. Any refinancing of our substantial indebtedness could be at significantly higher interest rates, which will depend on the conditions of the markets (particularly given the disruptions to and extreme volatility in the capital markets from COVID-19) and our financial condition at such time, and may require us to comply with more onerous covenants, which could further restrict our business operations. Any refinancing may also increase the amount of our secured indebtedness. In addition, the terms of existing or future debt agreements may restrict us from consummating any of these alternatives. Likewise, any reorganizations or restructuring activities, corporate realignments, asset sales or divestitures, strategic partnerships or other actions that we take 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, or that they will result in their intended benefits. COVID-19 has had a significant impact on the financial markets, which could make it more difficult to consummate any refinancing or result in more onerous or expensive terms.

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, and the ability of our partners and suppliers, to obtain and protect patent and other intellectual property rights relating to our current and future technologies, processes and 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. That is, the issuance of a patent is not conclusive as to its claimed scope, validity or enforceability. Patent rights may be challenged, revoked, invalidated, infringed or circumvented by third parties. For example, 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 also 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 and involves complex legal and factual questions. 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.

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. 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. Upon the expiration or loss of intellectual property protection for a product, others may manufacture and distribute such patented product, which may result in the loss of a significant portion of our sales of that product.

We also rely on trade secrets and other unpatented proprietary information, which we generally seek to protect by confidentiality and nondisclosure agreements with our employees, consultants, advisors and partners. These agreements may not effectively prevent disclosure of confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure. For example, in August 2017, we filed a complaint against QuVa Pharma, Inc. (QuVa) 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 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[®]. For more information regarding this litigation, see Note 14. Commitments and Contingencies. 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 our employees, scientific consultants or partners develop inventions or processes that may be applicable to our existing products or products under development, such inventions and processes will not necessarily become our property and may remain the property of those persons or their employers.

Any failure by us to adequately protect our technology, trade secrets or proprietary know-how or to enforce our intellectual property rights could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 condition, results of operations and cash flows.

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 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 and may in the future be involved in 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 and may in the future be 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 DOJ for review. In some instances, the FTC has brought actions against brand and generic companies that have entered into such agreements, alleging that they violate antitrust laws. Even in the absence of an FTC challenge, other governmental or private litigants may assert antitrust or other claims relating to such agreements. Accordingly, we may receive formal or informal requests from the FTC or other governmental entities for information about any such settlement agreement we enter into, and there is a risk that the FTC or other governmental or private litigants may commence an action against us alleging violation of antitrust laws or other claims.

The U.S. Supreme Court, in *FTC v. Actavis*, determined that patent settlement agreements 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 the legality of such settlements would be based, or provide guidance on the precise circumstances under which such settlements would 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, including proposed class actions, brought by direct and indirect purchasers alleging that a patent settlement agreement with Impax Laboratories, LLC (now Amneal) regarding OPANA[®] ER was unlawful in violation of federal antitrust laws and various state laws.

There have been federal and state legislative efforts to overturn the *FTC v. Actavis* decision and make certain terms in patent settlement agreements *per se* unlawful. For example, some members of the U.S. Congress have proposed legislation that would limit the types of settlement agreements generic manufacturers and brand companies can enter into. The state of California recently enacted legislation, effective January 1, 2020, that deems a settlement of a patent infringement claim to be presumptively anticompetitive and allows the California Attorney General to seek monetary penalties if a generic company receives anything of value from the branded company and the generic company agrees to delay research and development, manufacturing, marketing or sales of the generic product for any period of time. The California law carves out from the definition of "anything of value" certain types of settlement terms and it allows the settling parties to rebut the presumption of anticompetitive harm.

We have significant goodwill and other intangible assets. Consequently, potential impairments 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, 2019 and 2018, goodwill and other intangibles comprised approximately 66% and 71%, 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, 2019 and 2018, we recorded asset impairment charges of \$0.5 billion and \$0.9 billion, respectively, which related primarily to goodwill and other intangible assets. Refer to Note 10. Goodwill and Other Intangibles for examples and a discussion of material impairment tests and impairment charges during the years ended December 31, 2019 and 2018. The procedures and assumptions used in our goodwill and other intangible assets impairment testing are discussed in Note 10. Goodwill and Other Intangibles.

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 future periods could be negatively impacted should additional impairments of our goodwill or other intangible assets occur.

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

The marketing and pricing of our products and services, including product promotion, educational activities, support of continuing medical education programs and other interactions with healthcare professionals, are governed by various laws and regulations, including FDA regulations and the Anti-Kickback Statute. 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 could be difficult and expensive for us to comply with, could delay our introduction of new products and could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, it is unclear at this time whether the October Proposed Rule revising safe harbors to the federal Anti-Kickback Statute to, among other things, add new safe harbors for certain value-based arrangements, will be adopted or, if adopted, what effect, if any, it would have on the cost of complying with and our ability to comply with the federal Anti-Kickback Statute or on our business.

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, financial condition, results of operations and cash flows. 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.

The FFDCA and FDA regulations and guidance restrict the ability of healthcare companies, such as our company, to communicate with patients, physicians and other third-parties about uses of prescription pharmaceuticals or devices that are not cleared or approved by the FDA, which are commonly referred to as “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.

In February 2014, Endo Pharmaceuticals Inc. (EPI) entered into a Deferred Prosecution Agreement and 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. (PPCI) entered into a CIA and plea agreement with the DOJ to resolve allegations regarding the promotion of MEGACE[®] ES, which was subsequently subsumed by EPI’s CIA. Those agreements placed 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 CIAs, including the engagement of an Independent Review Organization. In February 2020, Endo was notified that it had satisfied its CIA requirements and the 5-year term of Endo’s CIA has now concluded.

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, including withdrawal or suspension of existing products.

Governmental authorities including without limitation the FDA impose substantial requirements on the development, manufacture, holding, labeling, marketing, advertising, promotion, distribution and sale of therapeutic pharmaceutical products.

Regulatory approvals for the sale of any new product candidate may require preclinical studies and clinical trials that such product candidate is safe and effective for its 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 could enroll in clinical trials more slowly than expected or could drop out before or during clinical trials. In addition, we may 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 and 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 any of our clinical trials.

Compliance with clinical trial requirements and cGMP regulations requires significant expenditures and the dedication of substantial resources. 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. 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 have a material adverse effect on our business, financial condition, results of operations and cash flows.

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.

We may seek FDA approval for certain unapproved marketed products through the 505(b)(2) regulatory pathway. Even if we receive approval for an NDA under section 505(b)(2) of the FDCA, the FDA may not take timely enforcement action against companies marketing unapproved versions of the product; 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).

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.

The submission of an NDA, Supplemental New Drug Application (sNDA), ANDA, BLA or sBLA to the FDA with supporting clinical safety and efficacy data 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 vary substantially based on the type, complexity and novelty of the product candidate, typically takes years, if approved at all, and is subject to uncertainty. 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 approval by regulatory agencies may subject the marketing of our products to certain limits on indicated use. For example, 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. Additionally, reimbursement by government payers or other payers may not be approved at the price we intend to charge for our products. 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. We could also be at risk for the value of any capitalized pre-launch stock related to products under development. The factors could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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. For example, 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 Group to legal proceedings, penalties, fines and reputational damage. 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 other companies that compete against us.

In addition, after a product is approved or cleared for marketing, 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. For example, in May 2016, an FDA advisory panel recommended mandatory training of all physicians who prescribe opioids on the risks of prescription opioids. In 2016, the Centers for Disease Control and Prevention also issued a guideline for prescribing opioids for chronic pain that provides recommendations for primary care clinicians 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 opioid medications in an attempt to curb abuse. These or any new regulations or requirements could be difficult and expensive for us to comply with and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 incurred 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 business, financial condition, results of operations and cash flows.

Based on scientific developments, post-market experience, legislative or regulatory changes or other factors, 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 APIs, 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 or other impurities in products.

Also, the FDA may require labeling revisions, formulation or manufacturing changes and/or product modifications for new or existing products containing impurities. 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 approvals. Although we do not believe that the FDA would seek to remove a currently marketed product from the market unless the effects of alleged impurities are believed to indicate a significant risk to patient health, we cannot make any such assurance.

The FDA's exercise of its authority under the FDCA 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. For example, in 2015, the FDA sent letters to a number of manufacturers, including Endo, requiring that a randomized, double-blind, placebo-controlled clinical trial be conducted to evaluate the effect of TRT 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[®].

Post-marketing studies and other emerging data about marketed products, such as adverse event reports, may 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, ANDA or BLA and may withdraw approval if, among other reasons, post-marketing clinical or other experience, tests or data show that a product is unsafe for use under the conditions upon which it was approved or licensed, or if FDA determines that there is a lack of substantial evidence of the product's efficacy under the conditions described in its labeling.

In addition to the FDA and other U.S. regulatory agencies, non-U.S. regulatory agencies may have authority over various aspects of our business and may impose additional requirements and costs. 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. Future inspections may result in additional inspection observations or other corrective actions, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Several of our core products contain controlled substances. Stringent DEA and other governmental 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 could subject 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 manufacture or supply product and thus, our ability to market affected products. This could have a material adverse effect on our business, financial condition, results of operations and cash flows. See also the 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 product at the salable unit level through the distribution system. The DSCSA will be effective incrementally over a 10-year period from its enactment on November 27, 2013. Compliance with DSCSA and future U.S. federal or state electronic pedigree requirements could require significant capital expenditures, increase our operating costs and impose significant administrative burdens.

We cannot determine what effect changes in laws, 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 expanded or different labeling, additional testing, monitoring of patients, interaction with physicians, education programs for patients or physicians, curtailment of necessary supplies, limitations on product distribution, the recall or discontinuance of certain products and additional recordkeeping. Any such changes could result in additional litigation and may have a material adverse effect on our business, financial condition, results of operations 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 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 or joint venture arrangements. However, we may not be able to complete acquisitions, obtain licenses or enter into arrangements that meet our target criteria on satisfactory terms, if at all. For example, 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 or licenses, which could cause us to be unable to consummate acquisitions, licensing agreements or cause the ultimate price we pay to increase. If we fail to achieve our acquisition or licensing goals, our growth may be limited.

Acquisitions of companies may expose us to additional risks, which may be beyond our control and may have a material adverse effect on our business, financial condition, results of operations 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 may not achieve realization of expected benefits. 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 larger and more complex company;
- challenges in retaining existing customers and obtaining new customers;
- potential unknown liabilities or larger liabilities than projected;
- unforeseen increases to expenses or other adverse consequences associated with the transaction; and
- difficulties in coordinating a geographically dispersed organization.

In addition, any acquisitions 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 benefits of mergers and acquisitions 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 group 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 group 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 relating to such factors may be interrelated, and the impact to the combined group 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 relating to 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 and 2019. 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, we may be forced to sell assets in response to liquidation or other claims described herein, and 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 a material adverse effect on our business, financial condition, results of operations and cash flows.

The availability of third party reimbursement for our products is uncertain, and 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 products, (ii) refusing, in some cases, to provide any coverage for off-label uses for products and (iii) requiring or encouraging, through more favorable reimbursement levels or otherwise, the substitution of generic alternatives to branded products.

The Trump Administration also has been targeting pharmaceutical prices in ways that could affect reimbursement for our products. For example, beginning in January 2020, Medicare Advantage Plans are 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 costs by establishing an “international pricing index” that would be used as a benchmark in deciding how much to pay for Medicare Part B products. CMS issued an Advance Notice of Proposed Rulemaking for the Medicare Program that would reduce Part B 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 products. It is 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 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. The U.S. presidential election is also leading to significant policy proposals regarding healthcare and we cannot predict which policies will ultimately be adopted and how they would impact us.

New tariffs and evolving trade policy between the U.S. and other countries, including China, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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. Such 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, it could cause us to raise prices for our products, which may result in the loss of customers. 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 other materials used in our products, or our business may be adversely impacted by retaliatory trade measures taken by other countries, including restricted access to APIs or other materials used in our products, causing us to raise prices or make changes to our products. 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. For example, the Trump Administration has placed tariffs on certain goods imported from China. In January 2020, the U.S. and China agreed to roll back certain tariffs, expand trade purchases and renew commitments on intellectual property, technology transfer and currency practices. Nevertheless, given the volatility and uncertainty regarding the scope and duration of these tariffs and other aspects of U.S. foreign trade policy, the impact on our operations and results is uncertain and could be significant. Further governmental action related to tariffs, additional taxes, regulatory changes or other retaliatory trade measures could occur in the future. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

We may experience downward pricing pressure on our products due to social or political pressure, which would reduce our turnover and future profitability. Price increases have resulted in increased public and governmental scrutiny of the cost of pharmaceutical products. For example, U.S. federal prosecutors have issued subpoenas to pharmaceutical companies in connection with an investigation into pricing practices conducted by the DOJ. Several state attorneys general also have commenced drug pricing investigations and filed lawsuits against pharmaceutical companies, including PPI, and the U.S. Senate has 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 or maintain the prices of our products.

In addition, the Trump Administration and a number of federal legislators continue to scrutinize pharmaceutical prices and are seeking ways to lower prices. For example, the Trump Administration's "Blueprint" on pharmaceutical 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 December 2019, the Trump Administration, through the FDA, released a proposed rule and draft guidance that set forth two pathways for the legal importation of certain pharmaceutical products in an effort to control costs. Since these pathways are not yet effective and are subject to revision pending receipt of public comments, we cannot determine what effect these pathways may have on our business, financial condition, results of operations and cash flows. In addition, Congress has held a number of hearings related to pharmaceutical 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 pharmaceutical 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 prices of pharmaceutical products in the future.

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

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

Market perceptions are very important to our business, especially market perceptions of our group and brands and the safety and quality of our products. If we, our partners and suppliers or our brands suffer negative publicity, or if any of our products or similar products are subject to market withdrawal or recall or are proven to be, or are claimed to be, ineffective or harmful to consumers, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

For example, the pharmaceutical supply chain 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 about opioid abuse could negatively affect our business, financial condition and results of operations. In recent years, opioid abuse has received a high degree of media coverage. Unfavorable publicity regarding, for example, the use or misuse of oxycodone or other prescription opioid medications, the limitations of abuse-deterrent forms, public inquiries and investigations into drug abuse, including the abuse of prescription products, litigation or regulatory activity could adversely affect our reputation. Additionally, 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. Such negative publicity could have an adverse effect on the potential size of the market for new or existing products and could decrease turnover and royalties, any of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

We cannot predict with any certainty how existing laws may be applied or how laws or legal standards may change in the future. Current or future legislation, whether state or federal, or in any of the non-U.S. jurisdictions with authority over our operations, may have a material adverse effect on our business, financial condition, results of operations and cash flows. For example, the effect of H.R. 6, enacted in October 2018, is still uncertain.

In addition, in April 2018, New York enacted a statute called the Opioid Stewardship Act (the Stewardship Act), which, among other things, provided for certain manufacturers 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 combined 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 (MME) 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 as of February 18, 2020. 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 a material adverse effect on our business, financial condition, results of operations and cash flows.

In the meantime, in April 2019, New York enacted an excise tax on the first sale of every opioid unit in New York at the rate of one quarter of a cent per MME where wholesale acquisition cost (WAC) is less than \$0.50 and one and one half cents per MME where WAC is equal to or greater than \$0.50. For purposes of this statute, "opioid" does not include buprenorphine, methadone or morphine and "sale" does not include transfers of title from a manufacturer in New York to a purchaser outside New York when the opioid unit will be used or consumed outside New York.

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 for certain claims, reverses certain burdens of proof as to causation, allows the use of population-based evidence and restricts discovery of certain documents. The provinces of Alberta, Ontario and Newfoundland enacted similar legislation in 2019 and the province of Saskatchewan has announced that it expects to pass similar legislation in 2020. It is possible that these statutes, or similar statutes enacted by other jurisdictions, and resultant litigation, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In Canada, the prices of patented pharmaceutical products are subject to regulation by the PMPRB. Under the Canadian *Patent Act* and *Patented Medicines Regulations*, patentees of inventions that pertain to pharmaceutical products sold in Canada are required to file price and sales information about their patented pharmaceutical products with the PMPRB. The PMPRB reviews this information on an ongoing basis to ensure that the prices of patented pharmaceuticals sold in Canada are not excessive, based upon price tests established by the PMPRB. There is a risk that the price of our pharmaceutical products could be found to be excessive because the price as set at launch is non-compliant with the PMPRB's guidelines, or because our average sale prices over time are not compliant with the guidelines. Furthermore, amendments expected to come into force on July 1, 2020 will introduce a number of changes to the regulation of Canadian drug prices by the PMPRB. The PMPRB guidelines will be updated to introduce new price tests to account for changes introduced by the amendments. The application of the new price tests under the guidelines could result in the current prices of our pharmaceutical products being deemed to be excessive. Failure by us to comply with the current or future guidelines could ultimately result in us reducing the prices of the pharmaceutical 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 a material adverse effect on our business, financial condition, results of operations and cash flows.

It is possible that these or other changes in law could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Public concern around the abuse of opioids or other products, including without limitation law enforcement concerns over diversion or marketing practices, regulatory efforts to combat abuse, and litigation could result in costs to our business.

Media stories regarding drug abuse and diversion, including the abuse and diversion of prescription opioid medications and other controlled substances, are commonplace. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of opioids, the limitations of abuse-deterrent formulations, the ability of abusers to discover previously unknown ways to abuse our products, public inquiries and investigations into drug abuse or litigation or regulatory or enforcement activity regarding sales, marketing, distribution or storage of opioids could have a material adverse effect on our reputation, on the results of litigation and on our ability to attract or maintain relationships with third-party partners, including suppliers, vendors, advisors, distributors, manufacturers, collaboration partners, administrators and agents.

Manufacturers of prescription opioid medications have been the subject of significant civil and criminal investigatory and enforcement actions even in cases where such medications have received approval from the FDA or similar regulatory authorities. Numerous governmental and private persons and entities are pursuing litigation against opioid manufacturers, including us, as well as distributors and others, asserting alleged violations of various laws and regulations relating to opioids and/or other prescription medicines, relying on common law theories, and seeking to hold the defendants accountable for, among other things, societal costs associated with the misuse and abuse of prescription opioid medications as well as non-prescription opioids. There is a risk we will be subject to similar investigations, enforcement actions 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 proceedings could have a material adverse effect on our business, financial condition, results of operations and cash flows. In 2019, several manufacturers of prescription opioid medications commenced cases under Title 11 of the U.S. Code in order to address the large volume of claims asserted against them in such litigation. See Note 14. Commitments and Contingencies 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 2019, New York enacted an excise tax on opioids. 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.

Various government entities, including the U.S. Congress, state legislatures or other policy-making bodies in the U.S. or elsewhere may hold hearings, conduct investigations and/or issue reports calling attention to opioid misuse and abuse, and may mention or criticize the role of manufacturers, including us, in supplying or marketing opioid medications or failing to take adequate steps to detect or report suspicious orders or to prevent abuse and diversion. Press organizations have reported and likely will continue to report on these issues, and such reporting has and may further result in adverse publicity which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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, a 340B Pharmaceutical Pricing Agreement and agreements with the Department of Veterans Affairs 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 CMS, the Health Resources and Services Administration and the Department of Veterans Affairs on a periodic basis to facilitate rebate payments to the State Medicaid Programs, to set Medicare Part B reimbursement levels and to establish the prices that can be charged to certain purchasers, including 340B-covered entities and certain government entities. Any failure to comply with these laws and agreements could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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. Ongoing compliance with these program rules, including the requirement that we adopt reasonable assumptions where law, regulation and guidance do not address specific participation issues, may impact the level of rebates that we owe under the program. The Final Rule also expanded the scope of the Medicaid Drug Rebate program to apply to U.S. territories and, pursuant to further rulemaking, that requirement is now effective April 1, 2022, which will require operational adjustments and may result in additional rebate liability. Finally, despite an initial proposal, CMS has not defined the term “line extension” for the Medicaid Drug Rebate Program. CMS has indicated that manufacturers should rely on the statutory definition of that term and reasonable assumptions in determining which products should be subject to an alternative rebate calculation. In light of the lack of clear guidance on this issue, it is possible that CMS could in the future disagree with a manufacturer’s determination of which products should be subject to higher rebates under the “line extension” rebate calculation.

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 products 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 proceedings 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 Tax Cuts and Jobs Act of 2017 eliminated the Patient Protection and Affordable Care Act (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 have a material adverse effect on our business, financial condition, results of operations and cash flows.

In December 2018, 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 (known as the individual mandate) are no longer permissible under the U.S. Congress' taxing power, the entire PPACA is no longer constitutional. The decision was appealed to the U.S. Court of Appeals for the Fifth Circuit. In December 2019, the Fifth Circuit issued an opinion holding that, while the individual mandate was no longer constitutional, the case must be remanded to the district court to further evaluate whether the mandate can be severed from the PPACA or the entire PPACA must be stricken down. In January 2020, petitions for certiorari were filed requesting that the U.S. Supreme Court review the Fifth Circuit's decision and ultimately decide the constitutionality of the PPACA. In March 2020, the U.S. Supreme Court granted certiorari in the consolidated cases of *Texas v. California and California v. Texas*, both of which address the Fifth Circuit's decision to strike down the individual mandate, while sending back to the district court the question of the overall law's constitutionality. Changes in law resulting from this ongoing lawsuit or other court challenges to the PPACA could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

We primarily sell our branded and generic products 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 MCOs. Our current customer group reflects significant consolidation in recent years, marked by mergers and acquisitions and other alliances. For example, we understand that 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, participates in the Walgreens Boots Alliance Development GmbH GPO. Consolidations and joint purchasing arrangements such as these have resulted in increased pricing and other competitive pressures on pharmaceutical companies, including us. Additionally, the emergence of large buying groups representing independent retail pharmacies and other distributors and the prevalence and influence of MCOs and similar institutions have increased the negotiating power of these groups, enabling them to attempt to extract various demands, including without limitation price discounts, rebates and other restrictive pricing terms. These competitive trends could continue in the future and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Total turnover from direct customers that accounted for 10% or more of our total consolidated turnover during the years ended December 31, 2019 and 2018 are as follows:

	2019	2018
AmerisourceBergen Corporation	34%	32%
McKesson Corporation	26%	27%
Cardinal Health, Inc.	25%	26%

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 fail to pay us on a timely basis, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 DEA 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 group, 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 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, financial condition, results of operations and cash flows.

We rely on third parties to supply 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 parties, the regulatory compliance of these third parties and on the strength, validity and terms of our various contracts with these third parties. 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, or any termination by these third parties of their arrangements with us, which, in each case, 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 group, 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.

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 have a material adverse effect on our business, financial condition, results of operations and cash flows.

We are dependent on 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 impact our 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 effect on our business, financial condition, results of operations and cash flows.

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 products for which regulatory approval is being sought and to approved 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 our products. 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, outbreak and spread of viral or other diseases, 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 could be interrupted. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

For example, the manufacturing facilities qualified to manufacture the enzyme CCH, which is included in our current XIAFLEX[®] product and in certain product candidates under development, including for the treatment of 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 could disrupt the manufacturing processes and could limit the supply of CCH and/or 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 by 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 civil litigation.

We purchase certain API and other materials used in our manufacturing operations from foreign and U.S. suppliers. The price and availability of API and other materials is subject to volatility for a number of reasons, many of which may be outside of our control. 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 have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 products reliant upon our manufacturing operations.

The manufacture of biologic products requires significant expertise and capital investment. Although we manufacture CCH, which is included in our current XIAFLEX[®] product and in certain product candidates under development, including for the treatment of cellulite, 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 CCH and the active ingredient of TESTOPEL[®], which could delay, disrupt or halt our manufacture of such products and/or product candidates, result in product recalls or product liability claims, require write-offs or otherwise have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 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. In addition, H.R. 6 amends the CSA 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 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 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 condition, 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, financial condition, results of operations and cash flows. 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 2019, our ordinary shares traded between \$1.97 and \$12.49 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 raise 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 pharmaceutical products;
- 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 against us or others;
- reports of security analysts and rating agencies;
- judgments or settlements or reports of settlement negotiations concerning opioid-related litigation or claims, and/or other companies commencing cases under Title 11 of the U.S. Code to address opioid-related litigation liabilities; 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 EU (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.

We currently do not intend to pay any cash dividends in the foreseeable future on our ordinary shares. Additionally, while the Board has approved a share buyback program (the 2015 Share Buyback Program), of which there is approximately \$2.3 billion available as of December 31, 2019, 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 the Board 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 the Board deems relevant. 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 business and operations could be negatively affected by shareholder activism, which could cause us to incur significant expenses, hinder execution of our business strategy and impact our share price.

In recent years, shareholder activism involving corporate governance, strategic direction and operations has become increasingly prevalent. If we become the subject of such shareholder activism, their demands may disrupt our business and divert the attention of our management, employees and Board. Also, we may incur substantial costs, including legal fees and other expenses, related to such activist shareholder matters. Perceived uncertainties resulting from such activist shareholder matters may result in loss of potential business opportunities with our current and potential customers and business partners, be exploited by our competitors and make attracting and retaining qualified personnel more difficult. In addition, such shareholder activism may cause significant fluctuations in our share price based on temporary or speculative market perceptions, uncertainties or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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. Such efforts 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, we collect and maintain information, which includes confidential, proprietary and 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, ransomware, 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’ 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.

Any 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 our group and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Non-U.S. regulatory requirements vary, including with respect to the regulatory approval process, and failure to obtain regulatory approval or maintain compliance with requirements in non-U.S. 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 a particular country is generally required prior to manufacturing or marketing that product in that country. 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 guarantee approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country guarantee 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 varying and 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 non-U.S. turnover will be adversely affected.

We could be adversely affected by the risks associated with having operated a medical device manufacturing business.

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

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. Certain countries in which we operate have, or are developing, laws protecting the confidentiality of individually identifiable personal information, including patient health information. This includes federal and state laws and regulations in the U.S. as well as in Europe and other markets.

For example, California recently adopted the California Consumer Privacy Act of 2018 (CCPA), which provides new data privacy rights for consumers and new operational requirements for businesses. The CCPA went into effect on January 1, 2020 and establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the state of California and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Because the CCPA only recently went into effect, many of its requirements have not yet been interpreted by courts and best practices are still being developed, all of which increase the risk of compliance failure and related adverse impacts.

In addition, the EU's General Data Protection Regulation (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, which has extra-territorial scope and substantial fines for breaches (up to 4% of global annual turnover or €20 million, whichever is greater) 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.

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 have a material adverse effect on our business, financial condition, results of operations and cash flows.

We face risks relating to the exit of the United Kingdom from the EU.

On June 23, 2016, the United Kingdom held a remain-or-leave referendum on the United Kingdom's membership within the EU, 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 EU. On May 22, 2017, the Council of the EU (the Council), adopted a decision authorizing the opening of Brexit negotiations with the United Kingdom and formally nominated the European Commission as the EU negotiator. The Council also adopted negotiating directives for the talks. On January 9, 2020, a Withdrawal Agreement Bill was passed by the United Kingdom House of Commons and, subject to scrutiny by the United Kingdom House of Lords, the Withdrawal Agreement Bill approves an eleven-month transition period starting on January 31, 2020 in which the United Kingdom will cease to be a member of the EU, but will continue to follow the EU's rules and contribute to its budget. In the event a full trade deal is not reached between the United Kingdom and EU by the December 31, 2020 deadline and there is no further extension, trade relations between the United Kingdom and the EU will be governed by any terms agreed within this period or by the World Trade Organization Rules. The impact on our business as a result of Brexit will depend, in part, on the outcome of tariff, trade, regulatory and other negotiations and on the ultimate manner and timing of the United Kingdom's withdrawal from the EU. As a result, we face risks associated with the potential uncertainty and consequences that may follow Brexit, including with respect to volatility in financial markets, exchange rates and interest rates. These uncertainties could increase the volatility of, or reduce, our investment results in particular periods or over time. Brexit could adversely affect political, regulatory, economic or market conditions in the United Kingdom and in Europe and it could contribute to instability in global political institutions and regulatory agencies.

Similarly, 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 EU 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 EU. 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 EU 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 EU 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 EU will cease being enforceable in the United Kingdom absent special arrangements to the contrary. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

In 2019, approximately 4% 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. 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 where we source, 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, we perform certain of our R&D functions in 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 business, financial condition, results of operations and cash flows. 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 other countries' economic conditions, product pricing, political stability or the state of relations between any such countries are difficult to predict and could adversely affect our operations, payment and credit terms and our ability to collect foreign receivables. 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 business, financial condition, results of operations and cash flows. 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 effect on our business, financial condition, results of operations and cash flows.

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 have a material adverse effect on our business, financial condition, results of operations and cash flows.

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, 2019, we have total debt of approximately \$8.47 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, such as those resulting from the COVID-19 pandemic, which may further limit our ability to satisfy our financial obligations.

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, decreased revenues or increased costs and expenses related to the impact of COVID-19 on our business, 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 business, financial condition, results of operations and cash flows. 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 (particularly given the extreme volatility in the capital markets) and our financial condition at such time. In addition, we may be able to incur substantial additional indebtedness in the future, including secured indebtedness. If new indebtedness is added to our current debt levels, the related risks that we and our subsidiaries now face could intensify. At any time and from time to time, we may also be pursuing activities to extend our debt maturities, lower principal balances, reduce interest expense or obtain covenant flexibility. Activities could include, without limitation, one or more tender offers, exchange offers, debt-for-equity exchanges or consent solicitations. The terms of any such transactions, including the amount of any exchange consideration and terms of any refinanced debt, could potentially be negatively impacted by a downgrade of our debt ratings and could also be less favorable than we have been able to obtain in the past, including a requirement that we grant liens on our assets as collateral (resulting in an increase in our total outstanding secured indebtedness), as a result of changing market conditions and investment interest from the pandemic and its impact on our business and the financial markets, including requiring us to incur additional secured indebtedness. We cannot predict if or when we would conduct any such activity, whether any such activities will achieve their intended results or whether any such activity could impact our financial results or be dilutive.

While interest rates have been at record low levels in recent years (most recently as a result of economic conditions resulting from the COVID-19 pandemic), this low interest rate environment likely will not continue indefinitely. At December 31, 2019, approximately \$3.3 billion and \$0.3 billion of principal amounts outstanding under the Term Loan Facility and the Revolving Credit Facility (each as defined in Note 13. Debt), respectively, bear interest at variable rates. Any future borrowings by the Group could also have variable interest 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 have a material adverse effect on our business, financial condition, results of operations 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, at December 31, 2019, \$3.3 billion outstanding under the Term Loan Facility and \$0.3 billion outstanding under the Revolving Credit Facility, bears interest rates in relation to LIBOR. Any future amounts borrowed under the Term Loan Facility or Revolving Credit Facility would also bear interest rates in relation to LIBOR, depending on our interest election. On July 27, 2017, the Financial Conduct Authority in the United Kingdom announced that it would phase out LIBOR as a benchmark by the end of 2021. The Alternative Reference Rates Committee (ARRC), a steering committee comprised of large U.S. financial institutions, has proposed replacing LIBOR with a new index calculated by short-term repurchase agreements (the Secured Overnight Financing Rate (SOFR)). At this time, no consensus exists as to what rate or rates may become accepted alternatives to LIBOR, and it is impossible to predict whether and to what extent banks will continue to provide LIBOR submissions to the administrator of LIBOR, whether LIBOR rates will cease to be published or supported before or after 2021 or whether any additional reforms to LIBOR may be enacted in the United Kingdom or elsewhere. Such developments and any other legal or regulatory changes in the method by which LIBOR is determined or the transition from LIBOR to a successor benchmark may result in, among other things, a sudden or prolonged increase or decrease in LIBOR, a delay in the publication of LIBOR and changes in the rules or methodologies in LIBOR, which may discourage market participants from continuing to administer or to participate in LIBOR's determination and, in certain situations, could result in LIBOR no longer being determined and published. If LIBOR ceases to exist, we may need to renegotiate the Credit Agreement (as defined in Note 13. Debt) 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, financial condition, results of operations and cash flows.

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 and/or our 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 may 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. 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 pursue other alternatives, including proceedings under applicable insolvency laws relating to some or all of our business. The covenants are also subject to a number of exceptions, including the ability to incur certain additional amounts of secured and unsecured indebtedness, which could exacerbate any of these risks. Any or all of the above could have a material adverse effect on our business, financial condition, results of operations and cash flows. For a description of our indebtedness, see Note 13. Debt.

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 (the 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 have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, 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 expect Endo International plc 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 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, 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. 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 could affect recorded deferred tax assets and liabilities and increase our effective tax rate, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. The potential impact of changes in tax laws in such jurisdictions could have a material impact on the Group.

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 Endo International plc is incorporated in Ireland, the IRS may assert that it 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 transactions (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 expect Endo International plc 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 transactions 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 generally taxed at the 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 periodically assess our tax positions 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 business, financial condition, results of operations and cash flows for the period or periods for which the applicable final determinations are made.

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, among other jurisdictions, the U.S., Canada, India, 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 ended 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 U.S. 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, including the Canada Revenue Agency, are currently examining our non-U.S. tax returns. Additionally, other jurisdictions where we are not currently under audit remain subject to potential future examinations. 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 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 costs, 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 condition, results of operations and cash flows.

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 transactions, 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 exceeded 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 effect on our business, financial condition, results of operations and cash flows.

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. § 10.30) to request amendments to FDA standards;

- attempting to use the legislative and regulatory process to have products 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 products.

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, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. We cannot determine what effect Section 610 of the FCAA 2020 may have on limiting or preventing the success of pharmaceutical companies or other third parties in delaying generic competition.

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 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.

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 the Board 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.

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. 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 a 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.

Likely Future Developments

As further described below, the impact on our results of COVID-19 and related changes in economic conditions, including changes to consumer spending resulting from the rapid rise in local and national unemployment rates, are highly uncertain and, in many instances, outside of our control. The duration and severity of the direct and indirect effects of COVID-19 are evolving rapidly and in ways that are difficult to anticipate. There are numerous uncertainties related to the COVID-19 pandemic that have impacted our ability to forecast our future operations. The extent to which COVID-19 will affect our business, financial position and operating results cannot be predicted with certainty; however, any such impact could be material. Refer to “Principal Risks” of this report for further details.

COVID-19 Update and Other Key Trends

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China. In March 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. Many countries and localities have announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, suspending all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing shelter-in-place orders (subject to limited exceptions). We are closely monitoring the impact of COVID-19 on all aspects of our business, the pharmaceutical industry and the economy as a whole, including how it has and will continue to impact our workforce, our customers and the patients they serve, our manufacturing and supply chain operations, our research and development (R&D) programs and regulatory approval processes and our liquidity and access to capital. In addition to our existing business continuity plans, we have established a team, led by our President and Chief Executive Officer and our executive leadership team, which has developed and implemented a range of proactive measures to address the risks, uncertainties and operational challenges associated with COVID-19. This team is closely monitoring the rapidly evolving situation and is implementing plans intended to limit the impact of COVID-19 on our business so that we can continue to produce the critical care medicines that hospitals and healthcare providers need to treat patients, including those with COVID-19. Actions we have taken to date and expected key trends are further described below.

Workforce. We have taken, and will continue to take, proactive measures to provide for the well-being of our workforce around the globe while continuing to safely produce products upon which patients and their healthcare providers rely. In addition to employing and paying full wages to our workforce, we are providing additional compensation to certain of our on-site operations employees for the hours worked during the COVID-19 pandemic. We have implemented alternative working practices and mandatory work-from-home requirements for appropriate employees, inclusive of our executive leadership team. We have suspended international and domestic travel, increased our already-thorough cleaning protocols throughout our facilities and prohibited non-essential visitors from our sites. We have also implemented various social distancing, modified schedules, shift rotation and other similar policies at our manufacturing facilities. Certain of these measures have resulted in increased and unexpected costs and, as further described below, resulted in the prioritization of certain products in our production plans.

Customers and the Patients They Serve. We have experienced, and expect to continue to experience, changes in customer demand as the COVID-19 pandemic evolves. Beginning late in the first quarter of 2020, we experienced a significant increase in sales volumes for certain of our critical care products administered to patients infected with COVID-19, such as VASOSTRICT[®], ADRENALIN[®] and albuterol sulfate HFA inhaler, the authorized generic of Merck’s Proventil[®]. These higher volumes resulted from increased utilization and channel inventory stocking of these products, primarily to treat patients infected with COVID-19. Other products not used to treat COVID-19, such as everolimus tablets, a generic version of Novartis Pharmaceuticals Corporation’s Afinitor[®], have also experienced increased demand due to accelerated prescription fulfillment that we believe is a result of concerns of healthcare providers and consumers regarding their ability to access medications because of shelter-in-place and similar measures taken by governments. At the same time, certain products that are physician administered, including XIAFLEX[®] and SUPPRELIN[®] LA, began experiencing decreased demand during the last two weeks of the first quarter of 2020 due to a reduction in physician activity and a slowing of patient office visits resulting from shelter-in-place orders. Additionally, as a result of our work-from-home requirements, we have transitioned to a “virtual” engagement model to continue supporting healthcare professionals, patient care and access to medicines.

Manufacturing and Supply Chain Operations. As of the date of this report, our business has not experienced any material supply issues related to COVID-19 and our manufacturing and quality assurance facilities across the globe have continued to operate. We have taken, and plan to continue to take, commercially practical measures to keep these facilities open as they are critical to our ability to reliably supply required critical care and medically necessary products. These measures, including the implementation of social distancing, modified schedules, shift rotation and other similar policies at our manufacturing facilities, as well as changes in our workforce availability have impacted our manufacturing and supply chain productivity at certain of our facilities and resulted in the prioritization of certain products, such as VASOSTRICT®, in our production plans to provide for their continued availability during and after the pandemic. We believe that our diversified manufacturing footprint, which includes a combination of Endo owned and leased facilities located in the U.S. and India, supply agreements and strong business relationships with numerous contract manufacturing organizations throughout the world, including in the U.S., Canada, Europe and India, and our proven ability to be a preferred partner of choice to large pharmaceutical companies seeking authorized generic distributors for their branded products, is a critical factor to mitigate significant risks related to manufacturing and supply chain disruption. This footprint, overseen by our global quality and supply chain teams in Ireland, combined with a skilled management team with significant experience in manufacturing and supply chain operations, has enabled us to respond quickly and effectively to the evolving COVID-19 pandemic to date.

Clinical and Development Programs. We have a number of ongoing clinical trials. We are committed to the safety of our patients, employees and others involved in these trials. We are monitoring COVID-19 closely and continue to partner with the FDA on our ongoing clinical trials, regulatory applications and other R&D activities. Based on an assessment of our R&D programs, including our clinical trials, we have developed a plan and timeline for each study in order to enhance communication with patients, sites and vendors. However, we may experience delays in some of our clinical trials and product development and commercialization programs, including obtaining adequate patient enrollment, receiving regulatory approvals and successfully bringing product candidates to market. For example, as a result of COVID-19 and its impact on medical aesthetics physician office closures and consumer spending, we are planning on changing the anticipated product launch of collagenase clostridium histolyticum (CCH) for the treatment of cellulite in the buttocks, if approved, to 2021.

Key Trends. Although we did not experience significant disruptions to our business during the first quarter of 2020 from COVID-19, we have since experienced and expect that we, and our industry as a whole, will continue to experience a greater impact going forward. The most significant trends we face as a result of the COVID-19 pandemic include: (i) decreases in demand for certain of our physician administered products due to physician office closures and a decline in patients electing to be treated, (ii) potential temporary decreases to the supply of certain of our products due to modified production schedules to safely maintain operations in response to COVID-19 and other factors including, without limitation, workforce availability, (iii) potential idle capacity charges based on implementation of social distancing, modified schedules, shift rotation and other similar policies at our manufacturing facilities and (iv) potential delays in our ability to launch some new products due to production prioritization and economic conditions and other factors outside of our control. For further information regarding the impact of COVID-19 on the Group, please refer to “Principal Risks” within this report.

Our estimated revenue trends for the full year 2020 compared to the full year 2019 are set forth below. These estimated revenue trends reflect the current expectations of our management team based on information currently available to them. Our estimates are subject to significant risks and uncertainties that could cause our actual results to differ materially from those indicated below, including our assumptions about the duration and severity of COVID-19 and the impact of any related governmental, business or other actions, any of which could cause the impact of COVID-19 to be more significant than our current expectations.

- For the full year 2020, we expect increased revenues from our Sterile Injectables segment as compared to 2019, primarily driven by increased sales of VASOSTRICT®. Beginning late in the first quarter of 2020, we experienced a significant increase in sales volumes for VASOSTRICT® compared to pre-COVID-19 levels resulting from increased utilization and channel inventory stocking of this product, primarily to treat patients infected with COVID-19. We expect that there will be an increase in revenues in the second quarter of 2020 compared to the first quarter, primarily due to higher utilization and channel inventory stocking. During the second half of 2020, we anticipate a period of destocking with a subsequent return toward pre-COVID-19 purchasing levels. Additionally, we expect the increase in VASOSTRICT® in 2020 to be partially offset by decreases in certain other Sterile Injectables, primarily due to assumed competitive pressures not related to COVID-19.

- For the full year 2020, we expect a decline in revenues from the Specialty Products portfolio of our Branded Pharmaceuticals segment as compared to 2019. During the last two weeks of the first quarter of 2020, we began to experience decreased demand as compared to pre-COVID-19 levels for physician administered products, including XIAFLEX®, SUPPRELIN® LA and AVEED®, due to physician office closures and a decline in patients electing to be treated. We expect to see a continuation of the decline in demand for these products during the second quarter of 2020, followed by a gradual increase in volumes beginning in the second half of the year to the extent that physician and patient activities return toward pre-COVID-19 levels.
- For the full year 2020, we expect a decline in revenues from our Generic Pharmaceuticals segment as compared to 2019, driven by modified production schedules to safely maintain operations in response to COVID-19, which could result in potential temporary supply decreases and potential launch delays for certain medications in this segment, as well as continued competitive pressures on certain commoditized generic products not related to COVID-19. We expect this decline to be partially offset by sales resulting from certain 2019 product launches, as further described below, and increased demand compared to pre-COVID-19 levels resulting from the utilization of certain of our generic products used to treat patients infected with COVID-19.
- For the full year 2020, we expect declines in revenues from the Established Products portfolio of our Branded Pharmaceuticals segment and the International Pharmaceuticals segment as compared to 2019, primarily driven by competitive pressures impacting these product portfolios.

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

COVID-19

We are closely monitoring the impact of COVID-19 on all aspects of our business, the pharmaceutical industry and the economy as a whole, including how it has and will continue to impact our workforce, our customers and the patients they serve, our manufacturing and supply chain operations, our R&D programs and regulatory approval processes and our liquidity and access to capital. In addition, we have implemented plans intended to limit the impact of COVID-19 on our business so that we can continue to produce the critical care medicines that hospitals and healthcare providers need to treat patients, including those with COVID-19. The extent to which COVID-19 will impact our business, financial position and operating results cannot be predicted with certainty due to numerous uncertainties related to COVID-19, but any such impact could be material.

On March 27, 2020, the CARES Act was enacted by the U.S. government in response to the COVID-19 pandemic. The CARES Act, among other things, permits net operating loss (NOL) carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. In the first quarter of 2020, the Company has recorded a discrete tax benefit in continuing operations of \$137.3 million as a result of the change in the NOL carryback period. This tax benefit is a non-recognized subsequent event for the year ended December 31, 2019.

Impairments

As a result of certain business decisions that occurred during the first quarter of 2020, we tested the goodwill of our Paladin reporting unit for impairment as of March 31, 2020. The fair value of the reporting unit was estimated using an income approach that utilized a discounted cash flow model. The discount rate utilized in this test was 9.5%. This goodwill impairment

test resulted in a pre-tax non-cash goodwill impairment charge of \$32.8 million during the three months ended March 31, 2020, representing the remaining carrying amount. This impairment was primarily attributable to portfolio decisions and updated market expectations during the quarter.

In addition, we recorded \$63.8 million of pre-tax non-cash asset impairment charges during the three months ended March 31, 2020 related primarily to certain developed technology intangible assets that were tested for impairment following changes in market conditions and certain other factors impacting recoverability.

These impairment charges are non-recognized subsequent events for the year ended December 31, 2019.

Legal Accruals

Subsequent to December 31, 2019, adjustments were made to recognize litigation charges related to probable and estimable damages for matters that existed at December 31, 2019.

Directors and Secretary

The names of the persons who were directors at any time during the year ended December 31, 2019 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. (1)	(Appointed 08 November 2017)
William P. Montague	(Appointed 28 February 2014)
Todd B. Sisitsky (2)	(Appointed 05 May 2016)
Secretary	
Yoon Ah Oh	(Appointed 28 June 2018)
Assistant Secretary	
Deanna Voss	(Appointed 28 February 2014)

(1) On November 4, 2019, Dr. Mansukani, who has been a member of the Board since November 2017 and has served as the Senior Independent Director since April 2018, notified the Company of his intention to resign from the Board, effective immediately, in order to focus on his other commitments, including his recent appointment as chairman of the board of another company. There are no disagreements between Dr. Mansukani and the Company, the Company's management or Board on any matters relating to the Company's operations, policies or procedures.

(2) On April 23, 2019, Mr. Todd B. Sisitsky, who has been a director of Endo International plc (the "Company") since May 2016, notified the Company of his decision not to stand for reelection to the Company's Board of Directors (the "Board") at the Company's 2019 Annual General Meeting of Shareholders (the "Annual Meeting") in order to focus on his other commitments, including his position as managing partner of TPG Capital, co-head of the firm's global health investing platform and a member of the firm's executive committee. Mr. Sisitsky will continue to serve as a director of the Company until the expiration of his term at the Annual Meeting on June 11, 2019. There are no disagreements between Mr. Sisitsky and the Company, the Company's management or the Board on any matters relating to the Company's operations, policies or practices.

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 27. 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, 2019 in the share capital of Endo International plc were as follows:

Directors	Ordinary Shares at 31 December 2019 (1)			Ordinary Shares at 31 December 2018 (or date of appointment if later) (1)		
	Shares	Options (2)	Other Share Units (3)	Shares	Options (2)	Other Share Units (3)
Roger H. Kimmel	188,235	8,094	15,074	250,203	8,094	15,074
Paul Campanelli	675,829	2,008,234	2,535,826	344,138	2,008,234	2,284,772
Shane M. Cooke	82,074	—	—	56,244	—	—
Nancy J. Hutson, Ph.D.	71,438	8,094	6,515	43,455	13,185	6,515
Michael Hyatt	317,373	8,094	—	289,390	18,478	—
Sharad S. Mansukani, Ph.D.	—	—	—	43,540	—	—
William P. Montague	69,763	8,094	23,108	41,780	18,478	23,108
Secretary						
Yoon Ah Oh	10,857	20,183	37,939	4,302	20,183	32,866

(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.

Dividends

The Group did not pay any dividends to ordinary shareholders and minority interests during 2019.

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 sustainable value for our shareholders, our employees, our customers and the communities in which we live and work 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 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, (iv) Bribery and Corruption and (v) Business Continuity. 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 is unwavering, proactive and strategic as regulatory and public expectations continue to evolve. Living with integrity is the foundation for us to achieve our goals, and maintain a competitive advantage in today's marketplace. 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, employees and shareholders.

Code of Conduct

Endo's Code of Conduct (the "Code") governs the Group'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 Group'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, Group 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 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 2019 and 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 2019	Calendar Year 2018
Energy Consumption			
Electricity	Megawatts	88,480	69,491
Natural Gas	Centum Cubic Feet	33,412,291	28,231,843
Diesel Fuel.....	Gallons	330,612	206,592
Water Consumption.....	Gallons	131,750,011	107,822,632
Waste Generation			
Hazardous Waste	Tons	546	453
Non-Hazardous Incineration	Tons	829	476
Recycling			
Cardboard, Metal and Plastic	Tons	201	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 group's ability to deliver 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 2019, Endo donated 129,980 medicines serving approximately 419,362 patients across 44 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 group 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 group’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 2019	Calendar Year 2018
<i>Safety</i>			
OSHA Injury Rate	Per 100 Employees	1.1	1.2
Days Away, Restricted and Transferred	Rate	1.1	1.2
Recordable Injuries	Number	32	29
Total Manhours Site Worked.....	Hours	5,653,039	4,831,760
Number of Employees	Employees	2,350	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.

Business Continuity

Knowing how to respond in a time of emergency or disaster is critical to ensuring the continued safety of our employees and the ongoing sustainability of our business. At Endo, we have a comprehensive plan for preventing, responding to, and recovering from potential disruptions across the group. This includes procedures and practices to ensure safety and mitigate business disruptions and an overarching framework that governs how crises are managed. These plans were leveraged as part of the Endo's response to COVID-19. See Likely Future Developments for discussion of Endo's response to COVID-19.

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 differ 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 29. 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 all available information about the future, including risks and uncertainties related to COVID-19 as further described in Principal Risks section of this document, current and anticipated trading performance and 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 Auditors

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 auditors are 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 auditors are 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, 2020.

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/ Paul Campanelli

 Paul Campanelli
 Chairman

/s/ Blaise Coleman

 Blaise Coleman
 Director

May 07, 2020

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.

The directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website. Legislation in Ireland governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.



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 2019 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 2019;
- the Company Balance Sheet as at 31 December 2019;
- the Consolidated Profit and Loss 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;
- the accounting policies; and
- the notes to the 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 (2018: \$33 million) - Consolidated financial statements
- Based on 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.
- \$13.8 million (2018: \$20 million) - Company financial statements
- Based on 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 in excess of 94% of Group revenues, Group 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 Group total assets.



Key audit matters

- Provisions for Sales Deductions.
 - Goodwill Impairment Assessment - Generic Pharmaceuticals and International Pharmaceuticals Segments.
 - Intangible Assets Impairment Assessments - Developed Technology and In-Process Research and Development.
-



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

Provisions for Sales Deductions

Refer to Notes 2 and 23 to the consolidated financial statements.

As described in Note 2 to the consolidated financial statements, the amount of revenue recognized by the Company is determined by adjusting the fixed amount of the transaction price for management's 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 management collectively refer to as sales deductions.

We tested the effectiveness of controls over sales deductions, including controls over the assumptions used to estimate the corresponding provisions for sales deductions balance at year-end.

We developed an independent estimate for these provisions at December 31, 2019 using historical payment information, third party data as well as evaluating pricing changes, other competitive factors, and terms of the specific sales deduction programs. We compared this expectation to the provisions recorded by management.

As of December 31, 2019, provisions for sales deductions totalled \$660.3 million. These amounts relate primarily to the company's estimates of unsettled obligations for returns and allowances, rebates and chargebacks. The most significant sales deductions relate to rebates paid under Medicaid and Medicare for the Branded Pharmaceuticals segment, wholesaler chargebacks and rebates for the Sterile Injectables and Generic Pharmaceuticals segments, and sales returns for each of these three segments.

We considered the historical accuracy of the management's estimates in previous years by comparing historical provisions to rebate payments and credits processed in subsequent periods.

Management estimates the provisions for sales deductions based on factors such as 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 inventory levels, current contract sales terms with direct and indirect customers and other competitive factors.

We tested a sample of actual payments made and amounts credited to both direct and indirect customers to evaluate whether the payments and credits were made in accordance with the contractual and mandated terms of the Group's rebate programs and returns policy.

Provisions for sales deductions was determined to be a key audit matter as there is significant judgment exercised by management in developing these reserves, including determining appropriate assumptions related to customers' buying patterns and the estimated resulting contractual deduction rates, estimated customer inventory levels, and other competitive factors.



Goodwill Impairment Assessment - Generic Pharmaceuticals and International Pharmaceuticals Segments

Refer to Notes 2 and 10 to the consolidated financial statements.

As described in Notes 2 and 10 to the financial statements the goodwill balance for the Generic Pharmaceuticals and International Pharmaceuticals segments was \$35.2 million as of December 31, 2019. An impairment charge of \$171.9 million was recorded during the year ended December 31, 2019.

An impairment assessment is conducted as of October 1st each year or more frequently whenever events or changes in circumstances indicate that the asset might be impaired. Management performs the goodwill impairment test by comparing the fair value and carrying amount of each reporting unit. Management estimated the fair values of its reporting units using an income approach that utilises a discounted cash flow model.

The discounted cash flow models are dependent upon management's estimates of future cash flows and other factors such as estimates of (i) future operating performance, including future sales, long-term growth rates, operating margins, discount rates and variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions.

Goodwill impairment assessment for the Generic Pharmaceuticals and International Pharmaceuticals segments was determined to be a key audit matter as there was significant judgment and estimation by management when determining the fair value of the reporting segments, including determining assumptions related to future sales, long-term growth rates, operating margins, discount rates, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows, and future economic conditions.

We also focused on the adequacy of the disclosures including the disclosures made in note 30 "Subsequent events" on the non-recognised subsequent events.

We evaluated management's determination of the reporting units and tested the assignment of assets and liabilities to those reporting units.

We tested the effectiveness of controls relating to goodwill impairment assessment, including controls over the identification of triggering events, determination of reporting units and the estimation of each reporting unit's fair value including the development of assumptions used to estimate fair value.

We assessed whether there were any events or circumstances indicating that goodwill may not be recoverable and therefore required goodwill impairment tests in addition to the annual test conducted as of October 1st.

We tested management's process for developing the fair value estimate, which included evaluating the appropriateness of the discounted cash flow model.

We tested the completeness, accuracy, and relevance of underlying data used in the discounted cash flow model.

We evaluated whether the assumptions used to estimate fair value, including future sales, long-term growth rates, operating margins, discount rates, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows, and future economic conditions, were reasonable, which included considering historical performance and industry and economic forecasts.

Our procedures also included the involvement of our PwC specialists with skills and knowledge to assist us in evaluating the reasonableness of significant assumptions, including the discount rate and long-term growth rate assumptions.

We considered the adequacy of the disclosures included in the financial statements relating to the impairment assessment of goodwill - Generic Pharmaceuticals and International Pharmaceuticals Segments and the related non-recognised subsequent events.



Intangible Assets Impairment Assessments – Developed Technology and In-Process Research and Development
Refer to Notes 2 and 10 to the consolidated financial statements.

As described in Notes 2 and 10 to the consolidated financial statements, the Group has \$2,430.3 million of developed technology finite-lived intangible assets and \$93.9 million of in-process research and development indefinite-lived intangible assets as of December 31, 2019.

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 a finite-lived intangible asset that will continue to be used in the Company's operations is measured by comparing first the carrying amount of the asset to the forecasted undiscounted future cash flows related to the asset. If the undiscounted cash flows are less than the carrying value, an impairment loss is determined by calculating the difference between the discounted after-tax cash flows and the carrying value of the intangible asset.

Indefinite-lived intangible assets are tested for impairment annually and when events or changes in circumstances indicate that the asset might be impaired. As part of intangible asset impairment assessments for indefinite-lived intangible assets, management estimates the fair values of the Company's indefinite-lived intangible assets using a discounted cash flow model.

The cashflow projections and discounted cash flow models are dependent upon management's estimates of future cash flows and other factors such as estimates of future operating performance, including future sales, long-term growth rates, operating margins, discount rates, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows as well as future economic conditions.

The Company recognized total other intangible asset impairment charges of \$347.7 million during the year ended December 31, 2019.

The impairment assessments for the developed technology and in process research and development of intangible assets was determined to be a key audit matter as there was significant judgment and estimation by management when developing the fair value measurement of developed technology and in-process research and development intangible assets, including determining significant assumptions related to future sales, long-term growth rates, operating margins, discount rates, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows, and future economic conditions in determining the fair value of each intangible asset.

We also focused on the adequacy of the disclosures including the disclosures made in note 30 "Subsequent events" on the non-recognised subsequent events.

We tested the effectiveness of controls relating to the valuation of intangible assets, including controls over the identification of triggering events and development of assumptions used to estimate fair value.

We evaluated whether there were any events or circumstances indicating that indefinite and finite live intangible assets may be impaired and tested management's process for developing the estimate to determine if an impairment was required, which included evaluating the appropriateness of the cash flow projections and discounted cash flow model, as applicable; testing the completeness, accuracy, and relevance of underlying data used in the projections and the model.

We evaluated whether the assumptions related to future operating performance, including future sales, long-term growth rates, operating margins, discount rates, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows, and future economic conditions, were reasonable which included considering historical performance and industry and economic forecasts.

Our procedures also included the involvement of PwC professionals with specialised skills and knowledge to assist us in evaluating the reasonableness of the discount rate used in the cashflow analysis.

We considered the adequacy of the disclosures included in the financial statements relating to the impairment assessment of Intangible Assets – Developed Technology and In-Process Research and Development and the related non-recognised subsequent events.



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 (Generic Pharmaceuticals, Branded Pharmaceuticals, 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.

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. Certain centralised Group functions, including treasury, taxation, equity and stock compensation, goodwill and intangible assets, contingent consideration and consolidation and financial reporting were subject to full scope audit procedures by the PwC US component team.

Through the performance of full scope audits and specified audit procedures, we obtained coverage in excess of 94% of Group revenues, 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 Group total assets. 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 follows:

	<i>Group financial statements</i>	<i>Company financial statements</i>
Overall materiality	\$33 million (2018: \$33 million).	\$13.8 million (2018: \$20 million).
How we determined it	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.	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 \$2 million (group audit) (2018: \$1.5 million) and \$600,000 (company audit) (2018: \$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 Annual Report 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 2019 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 Directors' Responsibilities Statement set out on page 75, 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.

Other 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.

Prior financial year Non Financial Statement

We are required to report if the company has not provided the information required by Regulation 5(2) to 5(7) of the European Union (Disclosure of Non-Financial and Diversity Information by certain large undertakings and groups) Regulations 2017 in respect of the prior financial year. We have nothing to report arising from this responsibility.

Gareth Hynes
for and on behalf of PricewaterhouseCoopers
Chartered Accountants and Statutory Audit Firm
Dublin
7 May 2020

ENDO INTERNATIONAL PLC
CONSOLIDATED PROFIT AND LOSS ACCOUNT
YEARS ENDED DECEMBER 31, 2019 AND 2018
(In thousands, except per share data)

	Note	2019	2018
TURNOVER	5	\$ 2,914,364	\$ 2,947,078
Cost of sales	3	1,569,338	1,631,682
GROSS PROFIT		1,345,026	1,315,396
Selling, general and administrative expenses.....		632,420	646,037
Research and development expenses.....		130,732	185,826
Litigation-related and other contingency expenses	3,5,14	(6,289)	13,809
Asset impairment charges.....	9,10	526,082	916,939
Acquisition-related and integration items.....	5	(46,098)	21,914
OPERATING PROFIT.....		\$ 108,179	\$ (469,129)
INTEREST RECEIVABLE AND SIMILAR INCOME.....	3,13	(19,946)	(13,194)
INTEREST PAYABLE AND SIMILAR CHARGES.....	3,13	558,680	534,850
(GAIN) LOSS ON EXTINGUISHMENT OF DEBT	3,13	(119,828)	—
OTHER PROFIT, NET	18	16,677	(51,953)
LOSS FROM CONTINUING OPERATIONS BEFORE TAXATION		\$ (327,404)	\$ (938,832)
TAX EXPENSE (BENEFIT) FROM CONTINUING OPERATIONS	19	15,680	22,935
LOSS FROM CONTINUING OPERATIONS		\$ (343,084)	\$ (961,767)
DISCONTINUED OPERATIONS, NET OF TAX	3	(92,052)	(69,702)
LOSS FOR THE FINANCIAL YEAR.....		\$ (435,136)	\$ (1,031,469)
LOSS PER SHARE - BASIC:			
Continuing operations		\$ (1.52)	\$ (4.29)
Discontinued operations		(0.41)	(0.32)
Basic		<u>\$ (1.93)</u>	<u>\$ (4.61)</u>
LOSS PER SHARE - DILUTED:			
Continuing operations		\$ (1.52)	\$ (4.29)
Discontinued operations		(0.41)	(0.32)
Diluted		<u>\$ (1.93)</u>	<u>\$ (4.61)</u>
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:			
Basic	20	226,050	223,960
Diluted	20	226,050	223,960

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS
YEARS ENDED DECEMBER 31, 2019 AND 2018
(In thousands)

	Note	2019	2018
LOSS FOR THE FINANCIAL YEAR.....		\$ (435,136)	\$ (1,031,469)
Net unrealized loss on securities	6,15	—	—
Foreign currency translation gain (loss)	15	10,139	(19,408)
TOTAL OTHER COMPREHENSIVE LOSS		<u>\$ (424,997)</u>	<u>\$ (1,050,877)</u>

ENDO INTERNATIONAL PLC
CONSOLIDATED BALANCE SHEET
DECEMBER 31, 2019 AND 2018
(In thousands)

	Note	December 31, 2019	December 31, 2018
ASSETS			
<i>Non-current Assets</i>			
Intangible assets-Goodwill.....	10	\$ 3,595,184	\$ 3,764,636
Intangible assets-Other	10	2,571,267	3,457,306
Investments	6	—	738
Tangible assets	9	504,865	498,892
Operating Lease Assets.....	8	51,700	—
Other.....	22	80,293	67,671
<i>Current Assets</i>			
Stock.....	7	327,865	322,179
Debtors	22	556,365	616,490
Cash at bank and in-hand.....		1,454,531	1,149,113
Restricted cash		247,457	305,368
TOTAL ASSETS		\$ 9,389,527	\$ 10,182,393
EQUITY AND LIABILITIES			
<i>Capital and Reserves</i>			
Called up share capital presented as equity	16	\$ 68	\$ 68
Share premium account	16	6,140,397	6,140,505
Other reserves		(9,507,623)	(9,566,752)
Profit and loss account.....		2,488,114	2,927,896
Total equity shareholders' funds.....		\$ (879,044)	\$ (498,283)
<i>Creditors: amounts falling due within one year</i>			
Debenture loans-current portion.....	13	\$ 34,150	\$ 34,150
Operating lease liabilities.....	8	10,763	—
Trade and other creditors	23	1,084,444	1,544,655
		\$ 1,129,357	\$ 1,578,805
<i>Creditors: amounts falling due after more than one year</i>			
Debenture loans	13	\$ 8,359,899	\$ 8,224,269
Operating lease liabilities.....	8	48,299	—
Trade and other creditors	23	364,461	376,122
Total for creditors: amounts falling due after more than one year		\$ 8,772,659	\$ 8,600,391
Provision for liabilities	23	\$ 366,555	\$ 501,480
TOTAL EQUITY AND LIABILITIES		\$ 9,389,527	\$ 10,182,393

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 May 07, 2020 and signed on its behalf by:

/s/ Paul Campanelli

Paul Campanelli
Chairman

/s/ Blaise Coleman

Blaise Coleman
Director

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENT OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2019 AND 2018
(In thousands)

	2019	2018
OPERATING ACTIVITIES:		
Consolidated net loss	(435,136)	(1,031,469)
Adjustments to reconcile consolidated net loss to Net cash provided by operating activities:		
Depreciation and amortization	612,862	723,707
Stock step-up.....	—	261
Share-based compensation	59,142	54,071
Amortization of debt issuance costs and discount	18,107	20,514
Deferred income taxes	(5,561)	5,557
Change in fair value of contingent consideration	(46,098)	19,910
Gain on extinguishment of debt.....	(119,828)	—
Asset impairment charges	526,082	916,939
Gain on sale of business and other assets	(6,367)	(45,155)
Changes in assets and liabilities which provided (used) cash:		
Debtors	19,158	17,090
Stock.....	(27,139)	67,269
Prepaid and other assets	11,370	(12,797)
Accounts payable, accrued expenses and other liabilities	(513,246)	(425,336)
Income taxes payable/receivable	4,706	(43,291)
Net cash provided by operating activities	<u>98,052</u>	<u>267,270</u>
INVESTING ACTIVITIES:		
Purchases of tangible fixed assets.....	(63,854)	(83,398)
Capitalized interest payments.....	(3,833)	(3,549)
Product acquisition costs and license fees.....	—	(3,000)
Proceeds from sale of business and other assets, net.....	6,577	70,369
Other investing activities	912	1,678
Net cash provided by (used in) investing activities	<u>(60,198)</u>	<u>(17,900)</u>
FINANCING ACTIVITIES:		
Proceeds from issuance of notes.....	1,483,125	—
Principal payments on notes.....	(1,501,788)	—
Principal payments on term loans.....	(34,152)	(34,150)
Proceeds from draw of revolving debt	300,000	—
Principal payments on other indebtedness.....	(9,196)	(5,222)
Payments for debt issuance and extinguishment costs	(6,414)	—
Payments for contingent consideration	(16,822)	(37,758)
Payments of tax withholding for restricted shares	(10,156)	(5,375)
Exercise of options	4	933
Net cash (used in) provided by financing activities	<u>204,601</u>	<u>(81,572)</u>
Effect of foreign exchange rate.....	1,096	(1,975)
Movement in cash held for sale	—	—
NET INCREASE (DECREASE) IN CASH AT BANK AND ON-HAND AND RESTRICTED CASH AT BANK AND ON-HAND	243,551	165,823
CASH AT BANK AND ON-HAND AND RESTRICTED CASH AT BANK AND ON-HAND, BEGINNING OF PERIOD	1,476,837	1,311,014
CASH AT BANK AND ON-HAND AND RESTRICTED CASH AT BANK AND ON-HAND, END OF PERIOD.....	1,720,388	1,476,837
SUPPLEMENTAL INFORMATION:		

	<u>2019</u>	<u>2018</u>
Cash paid for interest	559,528	515,042
Cash paid for income taxes.....	14,875	17,639
Cash received from U.S. Federal tax refunds.....	—	—
Cash paid into Qualified Settlement Funds for mesh legal settlements	253,520	336,648
Cash paid out of Qualified Settlement Funds for mesh legal settlements	314,266	353,032
Other cash distributions for mesh legal settlements	15,330	25,222

ENDO INTERNATIONAL PLC
CONSOLIDATED RECONCILIATION OF SHAREHOLDERS' FUNDS
YEARS ENDED DECEMBER 31, 2019 AND 2018
(In thousands)

	Endo International plc Shareholders				Total
	Share Capital	Share Premium	Profit and Loss Account	Other Reserves	
BALANCE, DECEMBER 31, 2017	\$ 70	\$ 6,140,434	\$ 3,956,289	\$ (9,611,913)	\$ 484,880
Effect of adopting ASU 2016-16 (NOTE 16).....	—	—	3,076	—	3,076
BALANCE, January 1, 2018	\$ 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, 2018	\$ 68	\$ 6,140,505	\$ 2,927,896	\$ (9,566,752)	\$ (498,283)
Effect of adopting ASC 842 (NOTE 16)	—	—	(4,646)	—	(4,646)
BALANCE, January 1, 2019	\$ 68	\$ 6,140,505	\$ 2,923,250	\$ (9,566,752)	\$ (502,929)
Net loss	—	—	(435,136)	—	(435,136)
Other comprehensive loss	—	—	—	10,139	10,139
Compensation related to share-based awards	—	—	—	59,142	59,142
Exercise of options	—	—	—	4	4
Tax withholding for restricted shares	—	—	—	(10,156)	(10,156)
Other	—	(108)	—	—	(108)
BALANCE, DECEMBER 31, 2019	\$ 68	\$ 6,140,397	\$ 2,488,114	\$ (9,507,623)	\$ (879,044)

ENDO INTERNATIONAL PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2019 AND 2018

NOTE 1. DESCRIPTION OF BUSINESS

Endo International plc is an Ireland-domiciled specialty branded and generics pharmaceutical company that conducts business through its operating subsidiaries. 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

Significant Accounting Policies

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, long-lived assets, goodwill, other intangible assets, income taxes, contingencies, financial instruments 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 branded and generic products 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 MCOs. Customers in the managed 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, 2019 and 2018 are as follows:

	2019	2018
AmerisourceBergen Corporation	34%	32%
McKesson Corporation	26%	27%
Cardinal Health, Inc.	25%	26%

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

VASOSTRICT[®] accounted for 18%, 15% and 12% of our 2019 and 2018 total turnover, respectively. XIAFLEX[®] accounted for 11% of our 2019 total turnover. No other products accounted for 10% or more of our total turnover during the years ended December 31, 2019 or 2018.

We have agreements with certain third parties for the manufacture, supply and processing of certain of our existing pharmaceutical products. See Note 14. 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 business, financial condition, results of operations and cash flows in future periods, including in the near term.

Turnover Recognition and Sales Deductions. 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. 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 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, 2019 and 2018, our reserves for sales deductions totaled \$660.3 million and \$772.3 million, respectively. These amounts relate primarily to our estimates of unsettled obligations for returns and allowances, rebates and chargebacks. The most significant sales deductions relate to rebates paid under Medicaid and Medicare for the Branded Pharmaceuticals segment, wholesaler chargebacks and rebates for the Sterile Injectables and Generic Pharmaceuticals segments and sales returns for each of these three segments. 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 that 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 GPOs. For example, we are required to provide a discount on our brand-name products 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, MCOs, GPOs 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.

Prior to the adoption of ASC 606, the Group accounted for turnover recognition and sales deductions under *Accounting Standards Codification Topic 605, Revenue Recognition* (ASC 605).

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 when that right is conditioned on something other than the passage of time. 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 Accounts receivable.

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 12. Contract Assets and Liabilities.

R&D. Expenditures for R&D are expensed as incurred. Total R&D expenses include, among other things, the costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, clinical trials, materials, medical support of marketed products and certain upfront and milestone payments. R&D spending also includes enterprise-wide costs which support our overall R&D infrastructure. Tangible assets that are acquired or constructed for R&D 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 Sheet.

Cash at Bank and On-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 on-hand. At December 31, 2019 and 2018, cash at bank and on-hand were deposited in financial institutions and consisted almost entirely of immediately available fund balances. The Group maintains its cash deposits and cash at bank with financial institutions it believes to be well-known and stable.

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

Accounts Receivable. Accounts receivable are stated at their net realizable value and the Group maintains an allowance for doubtful accounts against gross accounts receivable. The allowance is not material to the Group's Consolidated Financial Statements at December 31, 2019 or 2018. In addition, our accounts receivable balance is 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 and accounts receivable. From time to time, we invest our excess cash in high-quality, liquid money market instruments maintained by major banks and financial institutions. We have not experienced any losses on our cash at bank and on-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 88% and 87% of our gross trade accounts receivable balances represent amounts due from three customers (Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation) at December 31, 2019 and 2018, respectively.

We do not currently expect our current or future exposures to credit losses to have a significant impact on us. However, our customers' ability to pay us on a timely basis, or at all, could be affected by factors specific to their respective businesses and/or by economic conditions, including those related to the COVID-19 pandemic, the extent of which cannot be fully predicted.

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 Sheet. The Group capitalizes stock costs associated with certain 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. 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. It includes materials, direct labor and an allocation of overhead, but excludes certain period charges and unallocated overheads that are charged to expense in the period in which they are incurred. Unallocated overheads can occur as a consequence of abnormally low production or idle facilities.

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 Assets. Tangible assets is 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 assets are capitalized as assets under construction. Once an asset has been placed into service, depreciation expense is taken on a straight-line basis over the estimated useful life of the related assets or, in the case of leasehold improvements and finance lease assets, over the shorter of the estimated useful life and the lease term. Depreciation is based on the following estimated useful lives, as of December 31, 2019:

	Range of Useful Lives, from:
Buildings	10 years to 30 years
Machinery and equipment.....	1 year to 15 years
Computer equipment and software	1 year to 10 years
Furniture and fixtures.....	1 year to 10 years

Depreciation expense is not recorded on assets held for sale. Gains and losses on disposals are included in Other expense (profit), net in the Consolidated Profit and Loss Account. As further described below under the heading “Long-Lived Asset Impairment Testing,” our tangible assets are also subject to impairment reviews.

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 assets, net in the Consolidated Balance Sheet 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 adopted ASC 842 on January 1, 2019. For further discussion of the adoption, refer to the “Recent Accounting Pronouncements Adopted or Otherwise Effective as of December 31, 2019” section below. ASC 842 applies to a number of arrangements to which the Group is party.

Whenever the Group enters into a new arrangement, it must determine, at the inception date, whether the arrangement is or contains a lease. This determination generally depends on whether the arrangement conveys to the Group the right to control the use of an explicitly or implicitly identified asset for a period of time in exchange for consideration. Control of an underlying asset is conveyed to the Group if the Group obtains the rights to direct the use of and to obtain substantially all of the economic benefits from using the underlying asset.

If a lease exists, the Group must then determine the separate lease and nonlease components of the arrangement. Each right to use an underlying asset conveyed by a lease arrangement should generally be considered a separate lease component if it both: (i) can benefit the Group without depending on other resources not readily available to the Group and (ii) does not significantly affect and is not significantly affected by other rights of use conveyed by the lease. Aspects of a lease arrangement that transfer other goods or services to the Group but do not meet the definition of lease components are considered nonlease components. The consideration owed by the Group pursuant to a lease arrangement is generally allocated to each lease and nonlease component for accounting purposes. However, the Group has elected, for all of its leases, to not separate lease and nonlease components. Each lease component is accounted for separately from other lease components, but together with the associated nonlease components.

For each lease, the Group must then determine the lease term, the present value of lease payments and the classification of the lease as either an operating or finance lease.

The lease term is the period of the lease not cancellable by the Group, together with periods covered by: (i) renewal options the Group is reasonably certain to exercise, (ii) termination options the Group is reasonably certain not to exercise and (iii) renewal or termination options that are controlled by the lessor.

The present value of lease payments is calculated based on:

- Lease payments—Lease payments include fixed and certain variable payments, less lease incentives, together with amounts probable of being owed by the Group under residual value guarantees and, if reasonably certain of being paid, the cost of certain renewal options and early termination penalties set forth in the lease arrangement. Lease payments exclude consideration that is not related to the transfer of goods and services to the Group.
- Discount rate—The discount rate must be determined based on information available to the Group upon the commencement of a lease. Lessees are required to use the rate implicit in the lease whenever such rate is readily available; however, as the implicit rate in the Group leases is generally not readily determinable, the Group generally uses the hypothetical incremental borrowing rate it would have to pay to borrow an amount equal to the lease payments, on a collateralized basis, over a timeframe similar to the lease term.

In making the determination of whether a lease is an operating lease or a finance lease, the Group considers the lease term in relation to the economic life of the leased asset, the present value of lease payments in relation to the fair value of the leased asset and certain other factors, including the lessee's and lessor's rights, obligations and economic incentives over the term of the lease.

Generally, upon the commencement of a lease, the Group will record a lease liability and a right-of-use (ROU) asset. However, the Group has elected, for all underlying assets with initial lease terms of twelve months or less (known as short-term leases), to not recognize a lease liability or ROU asset. Lease liabilities are initially recorded at lease commencement as the present value of future lease payments. ROU assets are initially recorded at lease commencement as the initial amount of the lease liability, together with the following, if applicable: (i) initial direct costs incurred by the lessee and (ii) lease payments made by the lessor, net of lease incentives received, prior to lease commencement.

Over the lease term, the Group generally increases its lease liabilities using the effective interest method and decreases its lease liabilities for lease payments made. For finance leases, amortization expense and interest expense are recognized separately in the Consolidated Profit and Loss Account, with amortization expense generally recorded on a straight-line basis over the lease term and interest expense recorded using the effective interest method. For operating leases, a single lease cost is generally recognized in the Consolidated Profit and Loss Account on a straight-line basis over the lease term unless an impairment has been recorded with respect to a leased asset. Lease costs for short-term leases not recognized in the Consolidated Balance Sheet are recognized in the Consolidated Profit and Loss Account on a straight-line basis over the lease term. Variable lease costs not initially included in the lease liability and ROU asset impairment charges are expensed as incurred. ROU assets are assessed for impairment, similar to other long-lived assets.

Prior to the adoption of ASC 842, the Group accounted for leases under *Accounting Standards Codification Topic 840, Leases* (ASC 840).

Cloud Computing Arrangements. The Group may from time to time incur costs in connection with hosting arrangements that are service contracts. Subsequent to the Group's January 1, 2019 adoption of Accounting Standards Update (ASU) No. 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* (ASU 2018-15), which is further described below, the Group capitalizes any such implementation costs, expenses them over the terms of the respective hosting arrangements and subjects them to impairment testing consistent with other long-lived assets.

Finite-Lived Intangible Assets. Our finite-lived intangible assets consist of license rights and developed technology. Upon acquisition, intangible assets are generally initially recorded at fair value if acquired in a business combination, or at cost if otherwise. There are several methods that can be used to determine fair value. For intangible assets, we typically use an income approach. This approach 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, an accelerated amortization 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 net profit and net profit per share to decrease. Amortization expense is not recorded on assets held for sale.

As further described below under the heading “Long-Lived Asset Impairment Testing,” our finite-lived intangible assets are also subject to impairment reviews.

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 (if applicable), contractual terms and various other competitive and regulatory issues.

License Rights. Our license rights subject to amortization have useful lives ranging from 12 years to 15 years, with a weighted average useful life of approximately 14 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 (if applicable), contractual terms and various other competitive, developmental and regulatory issues.

Long-Lived Asset Impairment Testing. Long-lived assets, including tangible 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. In-process research and development acquired in an asset acquisition is expensed in the period it is acquired, assuming the assets have no alternative future use to the Group. Otherwise, acquired in-process research and development is generally recognized as an indefinite-lived intangible asset. Such assets are generally initially recorded at fair value if acquired in a business combination, or at cost if otherwise. Indefinite-lived intangible assets are not subject to amortization. Instead, they are tested for impairment annually and when events or changes in circumstances indicate that the asset might be impaired. Our annual assessment is performed as of October 1. 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. An impairment assessment is conducted as of October 1, or more frequently whenever events or changes in circumstances indicate that the asset might be impaired.

We perform the goodwill impairment test by comparing the fair value and carrying amount of each reporting unit. 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. Contingent accruals and legal settlements are recorded in the Consolidated Profit and Loss Account as Litigation-related and other contingencies, net (or as Discontinued operations, net of tax in the case of vaginal mesh matters) when the Group determines that a loss is both probable and reasonably estimable. Legal fees and other expenses related to litigation are expensed as incurred and included in Selling, general and administrative expenses in the Consolidated Profit and Loss Account (or as Discontinued operations, net of tax in the case of vaginal mesh matters).

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 receivables from its insurance carriers only when the realization of the potential claim for recovery is considered probable.

Contingent Consideration. Certain of the Group's acquisitions involve the potential for future payment of consideration that is contingent upon the occurrence of a future event, such as (i) the achievement of specified regulatory, operational and/or commercial milestones or (ii) royalty payments, such as those relating to future product sales. Contingent consideration liabilities related to an asset acquisition are initially recorded when considered probable and reasonably estimable, which may occur subsequent to the acquisition date. Subsequent changes in the recorded amounts are recorded as adjustments to the cost of the acquired assets. Contingent consideration liabilities related to a business combination are initially recorded at fair value on 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 liabilities to their current estimated fair values, 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 Sheet.

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 \$63.1 million, \$49.6 million and \$42.0 million for the years ended December 31, 2019 and 2018, 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 tangible assets, amortization of intangible assets, lease costs, 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 17. 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, the Group has concluded that certain of its distinct and separable operations have functional currencies other than the U.S. dollar. 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 profit 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 assets, goodwill and other intangible assets, and related income statement amounts, such as depreciation expense, historical exchange rates are used for remeasurement. The net effect of remeasurement is included in Other expense (profit), 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 U.S. dollar are translated into U.S. dollars at end-of-period exchange rates. Profit and expenses are translated using average exchange rates in effect during the year. The net effect of translation, as well as any foreign currency gains or losses on intercompany transactions considered to be of a long-term investment nature, are recognized as foreign currency translation, a component of Other comprehensive income (loss). Upon the sale or liquidation of an investment in a foreign operation, the Group records a reclassification adjustment out of Other comprehensive income (loss) for the corresponding accumulated amount of foreign currency translation gain or loss.

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 statement 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 profit 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 profit, 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 Sheet.

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' funds.

Recent Accounting Pronouncements

Recently Issued Accounting Pronouncements Not Yet Adopted at December 31, 2019

In June 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments* (ASU 2016-13). ASU 2016-13, together with a series of subsequently-issued related ASUs, establishes new requirements for companies to estimate expected credit losses when measuring certain assets, including accounts receivables. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. With certain exceptions, this guidance requires adoption using a modified retrospective approach. This guidance is not expected to have a material impact on the Group's consolidated results of operations, financial position or disclosures.

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, which was January 1, 2018 for the Group. Early adoption is permitted. ASU 2018-18 is not expected to have a material impact on the Group's consolidated results of operations, financial position or disclosures.

Recent Accounting Pronouncements Adopted or Otherwise Effective as of December 31, 2019

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (ASU 2016-02) to establish a comprehensive new accounting standard for leases. ASU 2016-02, together with a series of subsequently-issued related ASUs, has been codified in ASC 842. ASC 842 supersedes the lease accounting requirements in ASC 840 and requires lessees to, among other things, recognize on the balance sheet ROU assets and ROU lease liabilities, representing the present value of future minimum lease payments, for most leases.

The Group adopted ASC 842 using the modified retrospective approach with an effective date of January 1, 2019 for leases that existed on that date.

The Group has elected to apply certain practical expedients permitted under the transition guidance within ASC 842 to leases that commenced before January 1, 2019, including the package of practical expedients, as well as the practical expedient permitting the Group to not assess whether certain land easements contain leases. Due to the Group's election of these practical expedients, the Group has carried forward certain historical conclusions for existing contracts, including conclusions relating to initial direct costs and to the existence and classification of leases.

On January 1, 2019, as a result of adopting ASC 842, the Group recognized new ROU assets, current lease liabilities and non-current lease liabilities associated with operating leases of \$59.4 million, \$11.0 million and \$57.3 million, respectively, which were recorded in the Consolidated Balance Sheet as Operating lease assets, Current portion of operating lease liabilities and Operating lease liabilities, less current portion, respectively. The following table shows the ROU asset rollforward at 31-December 2019.

ROU Assets:	Total
At January 1, 2019, before adoption of ASC 842	—
Impact of adoption of ASC 842.....	119,206.....
At January 1, 2019	119,206
New Leases	6,930
Amortization	(17,774)
Impact of foreign currency and other.....	131
At December 31, 2019.....	\$ 108,493

The Group also derecognized certain assets and liabilities related to existing build-to-suit lease arrangements for which construction was completed prior to the date of transition and recognized new finance lease ROU assets and lease liabilities related to those lease arrangements. The net effect of the Group's adoption of ASC 842 resulted in a net increase to accumulated deficit of \$4.6 million.

In August 2018, the FASB issued 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. The Group early adopted this guidance during the first quarter of 2019 on a prospective basis.

NOTE 3. DISCONTINUED OPERATIONS AND DIVESTITURES

Astora

The operating results of the Group's Astora business, which the Board 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, 2019 and 2018 (in thousands):

	2019	2018
Litigation-related and other contingencies, net	\$ 60,400	\$ 34,000
Loss from discontinued operations before income taxes.....	\$ (92,052)	\$ (69,702)
Income tax benefit.....	\$ —	\$ —
Discontinued operations, net of tax	\$ (92,052)	\$ (69,702)

Loss from discontinued operations before income taxes includes Litigation-related and other contingencies, net, mesh-related legal defense costs and certain other items.

The cash flows from discontinued operating activities related to Astora included the impact of net losses of \$92.1 million and \$69.7 million for the years ended December 31, 2019 and 2018, 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, 2019 and 2018. There was no depreciation or amortization during the years ended December 31, 2019 and 2018 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. 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 Pharma AG 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 expense (profit), net in the Consolidated Profit and Loss Account. Litha was part of the Group's International Pharmaceuticals segment. Litha did 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 Soar Cell 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 did 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, 2019 and 2018 (in thousands):

	Year Ended December 31, 2019		
	Continuing Operations	Discontinued Operations	Global Company
TURNOVER.....	\$ 2,914,364	\$ —	\$ 2,914,364
Cost of sales	1,569,338	—	1,569,338
GROSS PROFIT	\$ 1,345,026	\$ —	\$ 1,345,026
Selling, general and administrative expenses.....	632,420	30,521	662,941
Research and development expenses	130,732	—	130,732
Litigation-related and other contingency expenses	(6,289)	60,400	54,111
Asset impairment charges	526,082	—	526,082
Acquisition-related and integration items	(46,098)	—	(46,098)
OPERATING LOSS.....	\$ 108,179	\$ (90,921)	\$ 17,258
INTEREST RECEIVABLE AND SIMILAR INCOME	(19,946)	—	(19,946)
INTEREST PAYABLE AND SIMILAR CHARGES.....	558,680	—	558,680
(GAIN) LOSS ON EXTINGUISHMENT OF DEBT	(119,828)	—	(119,828)
OTHER PROFIT, NET	16,677	1,131	17,808
LOSS FROM CONTINUING OPERATIONS BEFORE TAXATION.....	\$ (327,404)	\$ (92,052)	\$ (419,456)
TAX BENEFIT FROM COINTINUING OPERATIONS.....	15,680	—	15,680
LOSS FROM CONTINUING OPERATIONS	\$ (343,084)	\$ (92,052)	\$ (435,136)
DISCONTINUED OPERATIONS, NET OF TAX	(92,052)	92,052	—
LOSS FOR THE FINANCIAL YEAR.....	\$ (435,136)	\$ —	\$ (435,136)

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
LOSS ON EXTINGUISHMENT OF DEBT	—	—	—
OTHER PROFIT, 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)

The Group did not have held for sale assets and liabilities as of December 31, 2019 or 2018.

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, 2019 or 2018 or had material restructuring liabilities at either December 31, 2019 or December 31, 2018. Employee separation benefits provided under an established severance plan are expensed when a liability is considered both probable and estimable. One-time employee separation benefits, retention and certain other employee benefit-related costs are expensed ratably over the requisite service period. Other restructuring costs are generally expensed as incurred.

2016 Generic Pharmaceuticals Restructuring Initiative

As part of the Generic Pharmaceuticals integration efforts initiated in connection with the acquisition of Par Pharmaceutical Companies, Inc. 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 Generic Pharmaceuticals Restructuring Initiative). This initiative included certain cost savings measures, including a reduction in headcount and the disposal of our Charlotte, North Carolina manufacturing 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.

The Group did not incur any material pre-tax charges as a result of the 2016 Generic Pharmaceuticals Restructuring Initiative during any of the years ended December 31, 2019 or 2018 and does not expect to incur additional material pre-tax restructuring-related expenses related to this initiative. Substantially all related cash payments were made by the end of 2017. Payments made in 2017 included \$10.7 million for previously-accrued employee separation and other benefit-related costs.

2016 Branded 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 Branded Pharmaceuticals segment sales organization during the fourth quarter of 2016 (the 2016 Branded Pharmaceuticals Restructuring Initiative), which included the elimination of an approximate 375-member Branded 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 Branded Pharmaceuticals Restructuring Initiative during any of the years ended December 31, 2019 or 2018 and does not expect to incur additional material pre-tax restructuring-related expenses related to this initiative. Substantially all related cash payments were made by the end of 2017. Payments made in 2017 included \$16.5 million for previously-accrued employee separation and other benefit-related costs and \$5.2 million for previously-accrued contract termination charges.

January 2017 Restructuring Initiative

On January 26, 2017, the Group announced a restructuring initiative implemented as part of an 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 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 R&D 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 Branded Pharmaceuticals segment, \$4.9 million was included in Corporate unallocated costs and \$3.3 million was included in the Generic Pharmaceuticals segment. These charges were included in Selling, general and administrative expenses in the Consolidated Profit and Loss Account. Of these amounts, \$12.4 million was paid in 2017 and \$2.7 million was paid in 2018.

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.

2017 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 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 expense (profit), net in the Consolidated Profit and Loss Account.

As a result of the 2017 Generic Pharmaceuticals Restructuring Initiative, the Group incurred pre-tax charges of \$61.6 million during the year ended December 31, 2018. The 2018 amount does not include the \$12.5 million gain on 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.

These charges are included in the Generic Pharmaceuticals segment. Accelerated depreciation, employee separation, retention and other benefit-related costs and charges to increase excess stock reserves are primarily 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 2017 Generic Pharmaceuticals 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 Generic Pharmaceuticals Restructuring Initiative is primarily included in Accounts payable and accrued expenses in the Consolidated Balance Sheet. Changes to this liability during the years ended December 31, 2019 and 2018 were as follows (in thousands):

	Employee Separation and Other Benefit- Related Costs	Other Restructuring Costs	Total
Liability balance as of January 1, 2018.....	\$ 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
Cash distributions.....	(4,239)	(48)	(4,287)
Liability balance as of December 31, 2019.....	\$ —	\$ —	\$ —

January 2018 Restructuring Initiative

In January 2018, the Group initiated a restructuring initiative that included a reorganization of its Generic Pharmaceuticals segment's R&D network, a further simplification of the Group's manufacturing networks and a company-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 during the year ended December 31, 2018.

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 Generic Pharmaceuticals segment, \$5.2 million are included in Corporate unallocated costs, \$3.9 million are included in the Sterile Injectables segment, \$3.1 million are included in the International Pharmaceuticals segment and \$0.7 million are included in the Branded Pharmaceuticals segment.

Employee separation, retention and other benefit-related costs are included in Cost of sales, Selling, general and administrative and R&D 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 Sheet. Changes to this liability during the years ended December 31, 2019 and 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
Cash distributions.....	(829)	(320)	(1,149)
Liability balance as of December 31, 2019.....	\$ —	\$ —	\$ —

NOTE 5. SEGMENT RESULTS

During the first quarter of 2019, the Group changed the names of its reportable segments. This change, which was intended to simplify the segments' names, had no impact on the Group's Consolidated Financial Statements or segment results for any of the periods presented. Following this change, the Group's four reportable business segments are Branded Pharmaceuticals, Sterile Injectables, Generic Pharmaceuticals and International Pharmaceuticals. These 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 segment 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; certain legal costs; 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 directly 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 total segment adjusted profit from continuing operations before income tax is equal to the combined results of each of its segments.

Branded Pharmaceuticals

Our Branded 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, AVEED[®], PERCOCET[®], TESTOPEL[®], LIDODERM[®], EDEX[®] and VOLTAREN[®] Gel, among others.

Sterile Injectables

Our 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, the authorized generic of Merck's Invanz[®], ephedrine sulfate injection and treprostinil for injection, among others.

Generic Pharmaceuticals

Our 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. The key products of this segment serve growing therapeutic areas, including attention deficit hyperactivity disorder, pain, women's health and oncology. This segment also included Litha and Somar, which were sold in the second half of 2017.

The following represents selected information for the Group's reportable segments for the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
Net turnover from external customers:		
Branded Pharmaceuticals.....	\$ 855,402	\$ 862,832
Sterile Injectables.....	1,063,131	929,566
Generic Pharmaceuticals.....	879,882	1,012,215
International Pharmaceuticals (1)	115,949	142,465
Total net turnover from external customers.....	<u>\$ 2,914,364</u>	<u>\$ 2,947,078</u>
Segment adjusted profit from continuing operations before income tax:		
Branded Pharmaceuticals.....	\$ 362,711	\$ 368,790
Sterile Injectables.....	780,799	695,363
Generic Pharmaceuticals.....	158,400	317,892
International Pharmaceuticals.....	44,758	59,094
Total segment adjusted profit from continuing operations before income tax	<u>\$ 1,346,668</u>	<u>\$ 1,441,139</u>

(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.

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, 2019 or December 31, 2018.

The table below provides reconciliations of our Total consolidated loss from continuing operations before income tax, which is determined in accordance with U.S. GAAP, to our total segment adjusted profit from continuing operations before income tax for the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
Total consolidated loss from continuing operations before income tax	\$ (327,404)	\$ (938,832)
Interest expense, net.....	538,734	521,656
Corporate unallocated costs (1)	168,136	200,592
Amortization of intangible assets.....	543,862	622,339
Stock step-up	—	261
Upfront and milestone payments to partners	6,623	45,108
Retention and separation benefits and other cost reduction initiatives (2).....	34,598	86,295
Certain litigation-related and other contingencies, net (3).....	(6,289)	13,809
Asset impairment charges (4)	526,082	916,939
Acquisition-related and integration items, net (5).....	(46,098)	21,914
(Gain) loss on extinguishment of debt.....	(119,828)	—
Foreign currency impact related to the remeasurement of intercompany debt instruments.....	4,362	(5,486)
Other, net (6).....	<u>23,890</u>	<u>(43,456)</u>
Total segment adjusted profit from continuing operations before income tax	<u>\$ 1,346,668</u>	<u>\$ 1,441,139</u>

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

(2) Amounts in 2019 include \$14.7 million of costs associated with retention bonuses awarded to certain senior management of the Group. Other amounts in 2019 related primarily to our restructuring and other cost reduction initiatives. Such amounts included employee separation costs of \$8.9 million and other charges of \$11.0 million. 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. See Note 4. Restructuring for discussion of our material restructuring initiatives.

(3) Amounts include adjustments to our accruals for litigation-related settlement charges and certain settlement proceeds related to suits filed by our subsidiaries. Our material legal proceedings and other contingent matters are described in more detail in Note 14. Commitments and Contingencies.

- (4) Amounts primarily relate to charges to impair goodwill and intangible assets as further described in Note 10. Goodwill and Other Intangibles as well as charges to write down certain tangible assets as further described in Note 4. Restructuring, Note 6. Fair Value Measurements and Note 9. Tangible Assets.
- (5) Amounts primarily relate to changes in the fair value of contingent consideration.
- (6) Amounts in 2019 include \$17.5 million for contract termination costs incurred as a result of certain product discontinuation activities in our International Pharmaceuticals segment and \$14.1 million for a premium associated with an extended reporting period endorsement on an expiring insurance program. The remaining amounts in 2019 and 2018 primarily relate to gains on sales of businesses and other assets, as further described in Note 18. Other Expense (Profit), Net.

During the years ended December 31, 2019 and 2018, the Group disaggregated 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.

	2019	2018
<i>Branded Pharmaceuticals:</i>		
<i>Specialty Products:</i>		
XIAFLEX®	\$ 327,638	\$ 264,638
SUPPRELIN® LA	86,797	81,707
Other Specialty (1)	105,241	98,230
Total Specialty Products	<u>\$ 519,676</u>	<u>\$ 444,575</u>
<i>Established Products:</i>		
PERCOCET®	\$ 116,012	\$ 122,901
TESTOPEL®	55,244	58,377
Other Established (2).....	164,470	236,979
Total Established Products.....	<u>\$ 335,726</u>	<u>\$ 418,257</u>
Total Branded Pharmaceuticals (3)	<u>\$ 855,402</u>	<u>\$ 862,832</u>
<i>Sterile Injectables:</i>		
VASOSTRICT®	\$ 531,737	\$ 453,767
ADRENALIN®.....	179,295	143,489
Ertapenem for injection	104,679	57,668
APLISOL®	61,826	64,913
Other Sterile Injectables (4).....	185,594	209,729
Total Sterile Injectables (3)	<u>\$ 1,063,131</u>	<u>\$ 929,566</u>
Total Generic Pharmaceuticals (5)	<u>\$ 879,882</u>	<u>\$ 1,012,215</u>
Total International Pharmaceuticals (6).....	<u>\$ 115,949</u>	<u>\$ 142,465</u>
Total turnover, net	<u>\$ 2,914,364</u>	<u>\$ 2,947,078</u>

- (1) Products included within Other Specialty are NASCOBAL® Nasal Spray and AVEED®. Beginning with our first-quarter 2019 reporting, TESTOPEL®, which was previously included in Other Specialty, has been reclassified and is now included in the Established Products portfolio for all periods presented.
- (2) Products included within Other Established include, but are not limited to, LIDODERM®, EDEX® and VOLTAREN® Gel.
- (3) Individual products presented above represent the top two performing products in each product category for the year ended December 31, 2019 and/or any product having turnover in excess of \$100 million during any of the years ended December 31, 2019 or 2018 or \$25 million during any quarterly period in 2019 or 2018.
- (4) Products included within Other Sterile Injectables include ephedrine sulfate injection, trestatinil for injection and others.
- (5) The 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. During 2019, colchicine tablets, which launched in July 2018, made up 6% of consolidated total turnover. 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 4% and 5% of consolidated total turnover in 2019 and 2018, 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, 2019 and 2018 (in thousands):

	2019	2018
Branded Pharmaceuticals	\$ 12,573	\$ 14,542
Sterile Injectables	14,287	10,500
Generic Pharmaceuticals	32,689	66,016
International Pharmaceuticals	4,234	4,925
Corporate unallocated	5,217	5,385
Total depreciation expense.....	<u>\$ 69,000</u>	<u>\$ 101,368</u>

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 Sheet include cash at bank and on-hand (including money market funds), restricted cash at bank and on-hand, accounts receivable, equity 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), accounts receivable, accounts payable and accrued expenses approximate their fair values.

The following table presents current and noncurrent restricted cash at bank and on-hand balances at December 31, 2019 and December 31, 2018 (in thousands):

	December 31, 2019	December 31, 2018
Restricted cash at bank and on-hand—current portion (1).....	\$ 247,457	\$ 305,368
Restricted cash at bank and on-hand—noncurrent portion (2).....	18,400	22,356
Restricted cash at bank and on-hand—total (3).....	<u>\$ 265,857</u>	<u>\$ 327,724</u>

(1) These amounts are reported in our Consolidated Balance Sheet as Restricted cash at bank and on-hand.

(2) These amounts are reported in our Consolidated Balance Sheet as Other assets.

(3) Approximately \$242.8 million and \$299.7 million of our restricted cash at bank and on-hand are held in QSFs for mesh-related matters at December 31, 2019 and December 31, 2018, respectively. The remaining restricted cash at bank and on-hand primarily relates to other litigation-related matters. See Note 14. 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.

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 the “Recurring Fair Value Measurements” section 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, 2019 and 2018 were as follows (in thousands):

	Fair Value Measurements at December 31, 2019 using:			
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	Total
<i>Assets:</i>				
Money market funds	\$ 427,033	\$ —	\$ —	\$ 427,033
<i>Liabilities:</i>				
Acquisition-related contingent consideration—current	\$ —	\$ —	\$ 6,534	\$ 6,534
Acquisition-related contingent consideration—noncurrent	\$ —	\$ —	\$ 23,123	\$ 23,123

	Fair Value Measurements at December 31, 2018 using:			
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	Total
<i>Assets:</i>				
Money market funds	\$ 137,215	\$ —	\$ —	\$ 137,215
<i>Liabilities:</i>				
Acquisition-related contingent consideration—current	\$ —	\$ —	\$ 36,514	\$ 36,514
Acquisition-related contingent consideration—noncurrent	\$ —	\$ —	\$ 80,189	\$ 80,189

At December 31, 2019 and December 31, 2018, money market funds include \$70.2 million and \$86.9 million, respectively, in QSFs to be disbursed to mesh-related or other product liability claimants. Amounts in QSFs are considered restricted cash at bank and on-hand. See Note 14. Commitments and Contingencies for further discussion of our product liability cases. At December 31, 2019 and December 31, 2018, the differences between the amortized cost and the fair value of our money market funds 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 is measured at fair value on a recurring basis using significant unobservable inputs (Level 3), for the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
Beginning of period	\$ 116,703	\$ 190,442
Amounts settled	(41,448)	(92,627)
Changes in fair value recorded in earnings	(46,098)	19,910
Effect of currency translation	500	(1,022)
End of period	\$ 29,657	\$ 116,703

At December 31, 2019, the fair value measurements of the contingent consideration obligations were determined using risk-adjusted discount rates ranging from approximately 9.5% to 15.0% (weighted average rate of approximately 10.9%). 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, net. Amounts recorded for the current and noncurrent portions of acquisition-related contingent consideration are included in Accounts payable and accrued expenses and Other liabilities, respectively, in our Consolidated Balance Sheet.

The following table presents changes to the Group's liability for acquisition-related contingent consideration during the year ended December 31, 2019 by acquisition (in thousands):

	Balance as of December 31, 2018	Changes in Fair Value Recorded in Earnings	Amounts Settled and Other	Balance as of December 31, 2019
Auxilium acquisition.....	\$ 14,157	\$ 777	\$ (1,727)	\$ 13,207
Lehigh Valley Technologies, Inc. acquisitions	34,700	(8,614)	(19,286)	6,800
VOLTAREN® Gel acquisition (1).....	56,240	(37,184)	(18,870)	186
Other	11,606	(1,077)	(1,065)	9,464
Total.....	\$ 116,703	\$ (46,098)	\$ (40,948)	\$ 29,657

(1) The change in fair value recorded in earnings includes the impact of certain competitive events occurring during 2019.

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	Changes in Fair Value Recorded in Earnings	Amounts Settled 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

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, 2019 and 2018 were as follows (in thousands):

	Fair Value Measurements during the Year Ended December 31, 2019 (1) using:			Total Expense for the Year Ended December 31, 2019
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	
Intangible assets, excluding goodwill (Note 10).....	\$ —	\$ —	\$ 229,680	\$ (347,706)
Certain tangible assets (Note 9)	—	—	—	(6,468)
Total.....	\$ —	\$ —	\$ 229,680	\$ (354,174)

	Fair Value Measurements during the Year Ended December 31, 2018 (1) using:			Total Expense for the Year Ended December 31, 2018
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	
Intangible assets, excluding goodwill (Note 10).....	\$ —	\$ —	\$ 239,857	\$ (230,418)
Certain tangible assets (Note 9)	—	—	—	(6,521)
Total.....	\$ —	\$ —	\$ 239,857	\$ (236,939)

(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.

The Group also performed fair value measurements in connection with its goodwill impairment tests. Refer to Note 10. Goodwill and Other Intangibles for additional information, including the valuation methodologies utilized.

NOTE 7. STOCK

Stock consists of the following at December 31, 2019 and December 31, 2018 (in thousands):

	December 31, 2019	December 31, 2018
Raw materials (1).....	\$ 124,171	\$ 122,825
Work-in-process (1).....	65,392	70,458
Finished goods (1).....	138,302	128,896
Total.....	<u>\$ 327,865</u>	<u>\$ 322,179</u>

(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 noncurrent stock and is not included in the table above. At December 31, 2019 and December 31, 2018, \$29.0 million and \$8.1 million, respectively, of noncurrent stock was included in Other assets in the Consolidated Balance Sheet. As of December 31, 2019 and December 31, 2018, the Group's Consolidated Balance Sheet included approximately \$17.6 million and \$12.5 million, respectively, of capitalized pre-launch stock related to products that were not yet available to be sold.

As of December 31, 2019 and 2018, \$39.8 million and \$31.2 million, respectively, of employee costs were capitalized as part of stock.

NOTE 8. LEASES

We have entered into contracts with third parties to lease a variety of assets, including certain real estate, machinery, equipment, automobiles and other assets.

Our leases frequently allow for lease payments that could vary based on factors such as inflation or the degree of utilization of the underlying asset and the incurrence of contractual charges such as those for common area maintenance or utilities.

Renewal and/or early termination options are common in our lease arrangements, particularly with respect to our real estate leases. Our ROU assets and lease liabilities generally exclude periods covered by renewal options and include periods covered by early termination options (based on our conclusion that it is not reasonably certain that we will exercise such options).

Our most significant lease is for our Malvern, Pennsylvania location. The initial term of the lease is through 2024 and includes three renewal options, each for an additional 60-month period. These renewal options are not considered reasonably certain of exercise and are therefore excluded from the ROU asset and lease liability.

We are party to certain sublease arrangements, primarily related to our real estate leases, where we act as the lessee and intermediate lessor. For example, we sublease portions of our Malvern, Pennsylvania facility to multiple tenants through sublease arrangements ending in 2024, with certain limited renewal and early termination options.

The following table presents information about the Group's ROU assets and lease liabilities at December 31, 2019 (in thousands):

Consolidated Balance Sheet Line Items		December 31, 2019
ROU assets:		
Operating lease ROU assets	Operating lease assets	\$ 51,700
Finance lease ROU assets	tangible assets , net	56,793
Total ROU assets		<u>\$ 108,493</u>
Operating lease liabilities:		
Current operating lease liabilities	Current portion of operating lease liabilities	\$ 10,763
Noncurrent operating lease liabilities ...	Operating lease liabilities, less current portion	48,299
Total operating lease liabilities		<u>\$ 59,062</u>
Finance lease liabilities:		
Current finance lease liabilities	Accounts payable and accrued expenses	\$ 5,672
Noncurrent finance lease liabilities	Other liabilities	31,312
Total finance lease liabilities		<u>\$ 36,984</u>

At December 31, 2018, our lease assets and liabilities determined in accordance with ASC 840, which related primarily to our Malvern, Pennsylvania lease that was accounted for as a build-to-suit lease arrangement, totaled \$49.0 million and \$36.1 million, respectively. Lease assets had a cost basis of \$98.3 million and accumulated depreciation of \$49.3 million and were reflected as Tangible assets, net in the Consolidated Balance Sheet. Lease liabilities consisted of current liabilities of \$5.3 million included in Accounts payable and accrued expenses and noncurrent liabilities of \$30.8 million included in Other liabilities.

The following table presents information about lease costs and expenses and sublease income for the year ended December 31, 2019 (in thousands):

Consolidated Profit and Loss Account Line Items		2019
Operating lease cost	Various (1)	\$ 13,648
Finance lease cost:		
Amortization of ROU assets	Various (1)	\$ 9,407
Interest on lease liabilities	Interest expense, net	\$ 1,986
Other lease costs and income:		
Variable lease costs (2)	Various (1)	\$ 9,653
Sublease income	Various (1)	\$ (3,689)

(1) Amounts are included in the Consolidated Profit and Loss Account based on the function that the underlying leased asset supports. The following table presents the components of such aggregate amounts for the year ended December 31, 2019 (in thousands):

	2019
Cost of sales	\$ 11,168
Selling, general and administrative	\$ 17,648
Research and development	\$ 203

(2) Amounts represent variable lease costs incurred that were not included in the initial measurement of the lease liability such as common area maintenance and utilities costs associated with leased real estate and certain costs associated with our automobile leases.

Expenses incurred under operating leases, determined in accordance with ASC 840, were \$18.7 million in 2018.

The following table provides the undiscounted amount of future cash flows included in our lease liabilities at December 31, 2019 for each of the five years subsequent to December 31, 2019 and thereafter, as well as a reconciliation of such undiscounted cash flows to our lease liabilities at December 31, 2019 (in thousands):

	Operating Leases	Finance Leases
2020.....	\$ 14,103	\$ 7,446
2021.....	13,262	7,593
2022.....	12,688	7,743
2023.....	10,017	7,897
2024.....	5,176	8,054
Thereafter.....	15,332	13,483
Total future lease payments.....	<u>\$ 70,578</u>	<u>\$ 52,216</u>
Less: amount representing interest.....	11,516	15,232
Present value of future lease payments (lease liability)	<u>\$ 59,062</u>	<u>\$ 36,984</u>

The Group's future minimum lease commitments as of December 31, 2018, as determined in accordance with ASC 840 and reported in the prior year, were as follows:

	Capital Leases (1)	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.....	<u>\$ 44,048</u>	<u>\$ 86,174</u>
Less: Amount representing interest.....	4,084	
Total present value of minimum payments	<u>\$ 39,964</u>	
Less: Current portion of such obligations	5,845	
Long-term capital lease obligations	<u>\$ 34,119</u>	

(1) The Malvern, Pennsylvania location's lease arrangement is included under Capital Leases.

The following table provides the weighted average remaining lease term and weighted average discount rates for our leases as of December 31, 2019:

	December 31, 2019
Weighted average remaining lease term (years), weighted based on lease liability balances:	
Operating leases.....	5.9 years
Finance leases	9.5 years
Weighted average discount rate (percentages), weighted based on the remaining balance of lease payments:	
Operating leases.....	5.8%
Finance leases	5.5%

The following table provides certain cash flow and supplemental noncash information related to our lease liabilities for the year ended December 31, 2019 (in thousands):

	2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash payments for operating leases	\$ 14,940
Operating cash payments for finance leases	\$ 2,000
Financing cash payments for finance leases	\$ 9,196
Lease liabilities arising from obtaining right-of-use assets:	
Operating leases	\$ 623
Finance leases	\$ 5,953

NOTE 9. TANGIBLE ASSETS

Changes in the amount of Tangible Assets for the year ended December 31, 2019 are set forth in the table below (in thousands).

<i>Cost:</i>	Land and Buildings	Machinery and Equipment	Leasehold Improvements	Computer Equipment and Software	Furniture and Fixtures	Assets under Construction	Total
At January 1, 2019	\$ 230,035	\$ 211,491	\$ 69,256	\$ 117,134	\$ 12,495	\$ 121,024	\$ 761,435
Additions (1)	49,716	56,888	9,934	8,359	954	(46,715)	79,136
Disposals, transfers, impairments and other (2)	6,115	(6,394)	(8,926)	(8,951)	(515)	(1,096)	(19,767)
Effect of currency translation	—	71	60	495	509	—	1,135
At December 31, 2019	\$ 285,866	\$ 262,056	\$ 70,324	\$ 117,037	\$ 13,443	\$ 73,213	\$ 821,939
<i>Accumulated Depreciation:</i>							
At January 1, 2019	\$ (69,656)	\$ (83,906)	\$ (30,600)	\$ (71,437)	\$ (6,944)	\$ —	\$ (262,543)
Additions	(17,670)	(22,012)	(7,337)	(20,696)	(1,285)	—	(69,000)
Disposals, transfers and other (2)	2,850	1,605	1,110	8,617	515	—	14,697
Effect of currency translation	—	(44)	(31)	(142)	(11)	—	(228)
At December 31, 2019	\$ (84,476)	\$ (104,357)	\$ (36,858)	\$ (83,658)	\$ (7,725)	\$ —	\$ (317,074)
<i>Net Book Amount:</i>							
At December 31, 2019	\$ 201,390	\$ 157,699	\$ 33,466	\$ 33,379	\$ 5,718	\$ 73,213	\$ 504,865
At December 31, 2018	\$ 160,379	\$ 127,585	\$ 38,656	\$ 45,697	\$ 5,551	\$ 121,024	\$ 498,892

(1) Costs incurred during the construction or development of tangible assets are initially recorded as additions to Assets under Construction. Once an asset has been placed into service, the cost of that asset is transferred from Assets under Construction to one of the other classes of assets.

(2) Amounts include the effect of the Group's January 1, 2019 adoption of ASC 842, which is further described in Note 2. Summary of Significant Accounting Policies.

Depreciation expense was \$69.0 million and \$101.4 million for the years ended December 31, 2019 and 2018, respectively.

During the years ended December 31, 2019 and 2018, the Group recorded tangible assets impairment charges totaling \$6.5 million and \$6.5 million, respectively. These charges are included in the Asset impairment charges line item in our Consolidated Profit and Loss Account.

In 2019 and 2018, impairment charges reflect the write-off of certain tangible assets, including amounts that were abandoned or sold as part of our ongoing efforts to improve our operating efficiency and consolidate certain locations.

NOTE 10. 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, 2019	\$ 4,507,381	\$ 93,900	\$ 457,402	\$ 6,409	\$ 6,182,015	\$ 11,247,107
Additions	—	—	—	—	—	—
Impairments	(171,908)	—	—	—	(347,706)	(519,614)
Other (1)	—	—	—	—	(2,197)	(2,197)
Effect of currency translations ...	25,665	—	—	—	12,327	37,992
At December 31, 2019.....	\$ 4,361,138	\$ 93,900	\$ 457,402	\$ 6,409	\$ 5,844,439	\$ 10,763,288
Accumulated Amortization:						
At January 1, 2019	\$ (742,745)	\$ —	\$ (398,182)	\$ (6,409)	\$ (2,877,829)	\$ (4,025,165)
Charge	—	—	(12,154)	—	(531,708)	(543,862)
Other (1)	—	—	—	—	2,197	2,197
Effect of currency translations ...	(23,209)	—	—	—	(6,798)	(30,007)
At December 31, 2019.....	\$ (765,954)	\$ —	\$ (410,336)	\$ (6,409)	\$ (3,414,138)	\$ (4,596,837)
Net Book Amount:						
At December 31, 2019.....	\$ 3,595,184	\$ 93,900	\$ 47,066	\$ —	\$ 2,430,301	\$ 6,166,451
At January 1, 2019	\$ 3,764,636	\$ 93,900	\$ 59,220	\$ —	\$ 3,304,186	\$ 7,221,942

(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, 2019 and 2018 totaled \$543.9 million and \$622.3 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, 2019 is as follows (in thousands):

2020.....	\$ 437,420
2021.....	\$ 396,864
2022.....	\$ 381,312
2023.....	\$ 351,805
2024.....	\$ 308,986

Impairments

Goodwill and indefinite-lived intangible assets are tested for impairment annually and when events or changes in circumstances indicate that the asset might be impaired. Our annual assessment is performed as of October 1.

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 including estimates of (i) future operating performance, including future sales, long-term growth rates, operating margins, discount 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, 2019 and 2018 annual goodwill and indefinite-lived intangible assets impairment tests ranged from 9.5% to 13.5% and from 9.5% to 11.5%, 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, 2019 and 2018, the Group incurred the following goodwill and other intangible asset impairment charges (in thousands):

	2019	2018
Goodwill impairment charges	\$ 171,908	\$ 680,000
Other intangible asset impairment charges.....	\$ 347,706	\$ 230,418

A summary of significant goodwill and other intangible asset impairment tests and related charges is included below. Except as described below, pre-tax non-cash intangible asset impairment charges related 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, 2019, the Group determined that the estimated carrying amount of the Paladin reporting unit exceeded its fair value; therefore, the Group recorded a pre-tax non-cash goodwill impairment charge of \$20.8 million during the fourth quarter of 2019. The Paladin impairment was primarily a result of certain anticipated product discontinuation activities. The impairment also reflects the estimated impact of Canadian pricing regulations that were issued in the second half of 2019 and that we expect will become effective as early as July 2020. We did not record goodwill impairment charges for the other reporting units as a result of the 2019 annual tests.

As a result of our annual test performed as of October 1, 2018, the Group determined that the estimated carrying amounts of the 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 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 2018 annual tests.

Other Impairment Tests

As a result of certain competitive events that occurred during the first quarter of 2019, we tested the goodwill of our Generic Pharmaceuticals reporting unit for impairment as of March 31, 2019. The fair value of the reporting unit was estimated using an income approach that utilized a discounted cash flow model. The discount rate utilized in this test was 10.5%. This goodwill impairment test resulted in a pre-tax non-cash goodwill impairment charge of \$86.0 million during the three months ended March 31, 2019, representing the excess of this reporting unit's carrying amount over its estimated fair value. This Generic Pharmaceuticals impairment can be primarily attributed to the impact of the competitive events referenced above and an increase in the discount rate used in the determination of fair value.

During the second quarter of 2019, unfavorable competitive and pricing events occurred that caused us to update certain assumptions from those used in our first-quarter 2019 Generic Pharmaceuticals goodwill impairment test. The Group considered these events, together with the fact that this reporting unit's carrying amount equaled its fair value immediately subsequent to the first-quarter 2019 goodwill impairment charge, as part of its qualitative assessment of goodwill triggering events for the second quarter of 2019. As a result, we concluded that it was more likely than not that the fair value of this reporting unit was below its carrying amount as of June 30, 2019 and a goodwill impairment test was required. After performing this quantitative test, we determined that this reporting unit's carrying amount exceeded its estimated fair value. The fair value of the reporting unit was estimated using an income approach that utilized a discounted cash flow model. The discount rate utilized in this test was 10.5%. Based on the excess of this reporting unit's carrying amount over its estimated fair value, we recorded a pre-tax non-cash goodwill impairment charge of \$65.1 million during the three months ended June 30, 2019, representing the entire remaining amount of this reporting unit's goodwill.

During the first quarter of 2018, a change in segments resulted in changes to our reporting units for goodwill impairment testing purposes, including the creation of a new 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 Sterile Injectables and Generic Pharmaceuticals reporting units immediately after the segment realignment. These goodwill tests were performed using an income approach that utilized a discounted cash flow model. The results of these goodwill impairment tests were as follows:

- The former Generics reporting unit's estimated fair value exceeded its carrying amount, resulting in no related goodwill impairment charge.
- The new Sterile Injectables reporting unit's estimated fair value exceeded its carrying amount, resulting in no related goodwill impairment charge.
- The new Generic Pharmaceuticals reporting unit's carrying amount exceeded its estimated fair value, resulting in a pre-tax non-cash goodwill impairment charge of \$391.0 million.

NOTE 11. 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/or (ii) we are required to pay royalties on sales of the products arising from these agreements.

BioSpecifics Technologies Corp. (BioSpecifics)

The Group, through an affiliate, is party to a development and license agreement, as amended (the BioSpecifics Agreement) with 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 is included in our XIAFLEX[®] product. 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 DC, Dupuytren's nodules, PD, adhesive capsulitis, cellulite, plantar fibromatosis, lateral hip fat and other potential 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 may from time to time conduct exploratory clinical trials evaluating CCH as a treatment for a number of conditions, including uterine fibroids. In certain cases, the Group has the option to license development and marketing rights to future 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 and/or any of its sublicensees. We are also obligated to pay a percentage of any future regulatory or commercial milestone payments received from any 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.

Nevakar, Inc.

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. Pursuant to this agreement, Nevakar, Inc. 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 R&D 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 12. 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, 2019, 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, 2019	December 31, 2018	\$ Change	% Change
Contract assets, net (1)	\$ —	\$ 12,065	\$ (12,065)	(100)%
Contract liabilities, net (2).....	\$ 6,592	\$ 19,217	\$ (12,625)	(66)%

- (1) At December 31, 2018, approximately \$9.3 million of the contract asset amount is classified as a current asset and is included in Prepaid expenses and other current assets in the Group's Consolidated Balance Sheet. The remaining amount is classified as noncurrent and is included in Other assets. The net decrease in contract assets during the year ended December 31, 2019 was primarily due to 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, as well as certain product discontinuation activities in our International Pharmaceuticals segment.
- (2) At December 31, 2019 and December 31, 2018, approximately \$1.4 million and \$1.7 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 Sheet. The remaining amounts are classified as noncurrent and are included in Other liabilities. During the year ended December 31, 2019, the Group entered into new contracts resulting in an increase to contract liabilities of approximately \$4.0 million. This increase was more than offset by approximately \$14.9 million in reductions following certain product discontinuation activities in our International Pharmaceuticals segment and approximately \$1.2 million in turnover recognized during the period.

During the year ended December 31, 2019, we recognized turnover of \$10.8 million (2018:\$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 13. DEBT

The following table presents information about the Group's total indebtedness at December 31, 2019 and December 31, 2018 (dollars in thousands):

	December 31, 2019			December 31, 2018		
	Effective Interest Rate	Principal Amount	Carrying Amount	Effective Interest Rate	Principal Amount	Carrying Amount
7.25% Senior Notes due 2022	7.25%	\$ 8,294	\$ 8,294	7.91%	\$ 400,000	\$ 392,947
5.75% Senior Notes due 2022	5.75%	182,479	182,479	6.04%	700,000	694,464
5.375% Senior Notes due 2023	5.62%	210,440	209,018	5.62%	750,000	743,438
6.00% Senior Notes due 2023	6.28%	1,439,840	1,426,998	6.28%	1,635,000	1,616,817
5.875% Senior Secured Notes due 2024.....	6.14%	300,000	296,647	6.14%	300,000	296,062
6.00% Senior Notes due 2025	6.27%	1,200,000	1,185,726	6.27%	1,200,000	1,183,415
7.50% Senior Secured Notes due 2027.....	7.71%	1,500,000	1,482,212	—	—	—
Term Loan Facility	6.21%	3,329,625	3,302,675	7.02%	3,363,775	3,331,276
Revolving Credit Facility	4.25%	300,000	300,000	—	—	—
Total long-term debt, net		\$ 8,470,678	\$ 8,394,049		\$ 8,348,775	\$ 8,258,419
Less current portion, net		34,150	34,150		34,150	34,150
Total long-term debt, less current portion, net		\$ 8,436,528	\$ 8,359,899		\$ 8,314,625	\$ 8,224,269

The Group and its subsidiaries, with certain customary exceptions, guarantee or serve as issuers or borrowers of the debt instruments representing substantially all of the Group's indebtedness at December 31, 2019. The obligations under (i) all of the senior secured notes and (ii) the Credit Agreement (as defined below) and related loan documents 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 the 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 \$7.4 billion and \$7.2 billion at December 31, 2019 and December 31, 2018, 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 \$1,000.0 million senior secured revolving credit facility (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). Current amounts outstanding under the Credit Facilities are set forth in the table above. After giving effect to borrowings under the Revolving Credit Facility and previously issued and outstanding letters of credit, approximately \$696.8 million of remaining credit is available under the Revolving Credit Facility as of December 31, 2019. The Group's outstanding debt agreements contain a number of restrictive covenants, including certain limitations on the Group's ability to incur additional indebtedness.

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, 2019 and December 31, 2018, we were in compliance with all such covenants.

In addition, after each fiscal year-end, 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, 2019.

The commitments under the Revolving Credit Facility generally mature in 2024, with the exception of \$76.0 million of commitments that mature 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 ultimate maturity date in 2024, at which time the remaining principal amount outstanding will be payable. However, with certain exceptions set forth in the Credit Agreement, maturities under the Credit Facilities will be accelerated if any of the following of our senior notes are not refinanced or repaid in full at least 91 days prior to the respective maturity dates 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

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 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) 3.25% 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 2027. 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 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 each indenture and (iii) accrued and unpaid interest. As of December 31, 2019, the Non-Call Period has expired for each of our notes except for the 5.875% Senior Secured Notes due 2024, the 6.00% Senior Notes due 2025 and the 7.50% Senior Secured Notes due 2027.
- 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 100.000% to 105.625% of principal at December 31, 2019; 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, 2019, this clause has expired for each of our notes except for the 5.875% Senior Secured Notes due 2024 and the 7.50% Senior Secured Notes due 2027, for which the specified redemption premiums are 105.875% and 107.500%, respectively.

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 indentures, the negative covenants, among other things, restrict the Group's ability and the ability of its restricted subsidiaries (as defined in the indentures) 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. Under the senior unsecured notes indentures, the negative covenants, among other things, restrict the ability of Endo Designated Activity Group and its restricted subsidiaries (as defined in the indentures) 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 issuer or any of the restricted subsidiaries; create certain liens; merge, consolidate or sell all or substantially all of Endo Designated Activity Group'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 senior secured notes, upon the notes receiving investment grade credit ratings. As of December 31, 2019 and December 31, 2018, 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.

Debt Financing Transactions

Set forth below are certain disclosures relating to debt financing transactions that occurred during the years ended December 31, 2019 and 2018.

March 2019 Refinancing

In March 2019, the Group executed certain transactions (the March 2019 Refinancing Transactions) that included:

- entry into an amendment (the Revolving Credit Facility Amendment) to the Group's existing credit agreement, which was originally dated April 27, 2017 (the amended credit agreement is described above under the heading "Credit Agreement");
- issuance of \$1,500.0 million of 7.50% Senior Secured Notes due 2027 (the 2027 Notes);
- 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
- 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 to 1.00 to 4.50 to 1.00 and (iii) limit the scenarios under which such Financial Covenant will be tested.

The 2027 Notes were issued by PPI, a wholly-owned indirect subsidiary of the Group, 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 Group 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 Group'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 generally allow 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.
- 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. 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.

The Group used the net proceeds from the 2027 Notes and cash on 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 Group'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. 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 a partial offset to the gain. 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 to be amortized as interest expense over the terms of the respective instruments. The net gain resulting from the March 2019 Refinancing Transactions was included in the (Gain) loss on extinguishment of debt line item in the Consolidated Profit and Loss Account.

June 2019 Revolving Credit Facility Borrowing

In June 2019, the Group borrowed \$300.0 million under the Revolving Credit Facility. These proceeds will be used for purposes consistent with the Group's capital allocation priorities, including for general corporate purposes.

Maturities

The following table presents the maturities on our long-term debt for each of the five fiscal years subsequent to December 31, 2019 (in thousands):

	Maturities (1)
2020.....	\$ 34,150
2021.....	\$ 34,150
2022 (2).....	\$ 247,723
2023.....	\$ 1,684,430
2024 (2).....	\$ 3,770,225

- (1) 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 seek to repay or refinance certain senior notes prior to their stated maturity dates. The amounts in this maturities table do not reflect any such early repayment or refinancing; rather, they reflect stated maturity dates.
- (2) Based on the Group's borrowings under the Revolving Credit Facility that were outstanding at December 31, 2019, \$22.8 million will mature in 2022, with the remainder maturing in 2024.

NOTE 14. 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 a material 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 an 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 \$8.6 million and \$7.5 million for the years ended December 31, 2019 and 2018, respectively.

Milestones and Royalties

See Note 11. License and Collaboration Agreements for a description of future milestone and royalty commitments pursuant to our material 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, tax 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. An adverse outcome in any of these proceedings could have a material adverse effect on our business, financial condition, 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 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 stated coverage limits and may not be adequate to cover damages, other relief and/or costs relating to claims. In addition, there is no guarantee that insurers will pay claims or that coverage will otherwise be available. See the principal risk “We may not have and may be unable to obtain or maintain insurance adequate to cover potential liabilities” for more information.

As of December 31, 2019, our accrual for loss contingencies totaled \$500.0 million (2018: \$955.1 million), the most significant components of which relate to product liability and related matters associated with transvaginal surgical mesh products, which we have not sold since March 2016. 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. While the timing of the resolution of certain of the matters accrued for as loss contingencies remains uncertain and could extend beyond 12 months, as of December 31, 2019, the entire liability accrual amount is classified in the Current portion of legal settlement accrual in the Consolidated Balance Sheet.

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, and in Canada, Australia and other countries, alleging personal injury resulting from the use of certain products of our subsidiaries, including the product liability and other related matters described below in more detail.

Vaginal Mesh. Since 2008, we and certain of our subsidiaries, including American Medical Systems Holdings, Inc. (AMS) (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 multidistrict litigation (MDL) in the U.S. District Court for the Southern District of West Virginia), and in Canada, Australia 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). Our subsidiaries have not sold such products since March 2016. 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.

Various Master Settlement Agreements (MSAs) and other agreements have resolved up to approximately 71,000 filed and unfiled U.S. mesh claims. 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 the settlement funds will be deposited, establish participation requirements and allow for a reduction of the total settlement payment in the event participation thresholds are not met. Funds deposited in QSFs are considered restricted cash at bank and on-hand. Distribution of funds to any individual claimant is conditioned upon the receipt of documentation substantiating product use, 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.

In October 2019, the Ontario Superior Court of Justice approved a class action settlement covering unresolved claims by Canadian women implanted with an AMS vaginal mesh device. Astora funded the settlement in February 2020.

The following table presents the changes in the QSFs and mesh liability accrual balances during the year ended December 31, 2019 (in thousands):

	Qualified Settlement Funds	Mesh Liability Accrual
Balance as of January 1, 2019	\$ 299,733	\$ 748,606
Additional charges	—	60,000
Cash contributions to Qualified Settlement Funds	253,520	—
Cash distributions to settle disputes from Qualified Settlement Funds	(314,266)	(314,266)
Cash distributions to settle disputes	—	(15,330)
Other (1)	3,855	5,021
Balance as of December 31, 2019	<u>\$ 242,842</u>	<u>\$ 484,031</u>

(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. Also included within this line are foreign currency adjustments for settlements not denominated in U.S. dollars.

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, 2019, the Group has made total cumulative mesh liability payments of approximately \$3.5 billion, \$242.8 million of which remains in the QSFs as of December 31, 2019. We currently expect to fund the remaining payments under all previously executed settlement agreements into the QSFs during 2020. 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 on-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 on-hand.

We were contacted in October 2012 regarding a civil investigation initiated by various U.S. 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 the investigations.

The MDL court has been remanding MDL cases to their districts of origin for further proceedings. Other cases are proceeding in various state and federal courts. The earliest trial is currently scheduled for August 2020; however, trials may occur earlier or later as timing remains uncertain due to the impact of COVID-19 and other factors. 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.

Although the Group believes it has appropriately estimated the probable total amount of loss associated with all mesh-related matters as of the date of this report, litigation 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 overall liability accrual may be required. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Testosterone. A federal MDL in the U.S. District Court for the Northern District of Illinois has included multiple lawsuits against manufacturers of prescription medications containing testosterone, including our subsidiaries EPI and Auxilium Pharmaceuticals, Inc. (subsequently converted to Auxilium Pharmaceuticals, LLC and hereinafter referred to as Auxilium). Plaintiffs in these suits have generally alleged various personal injuries resulting from the use of such medications (including FORTESTA[®] Gel, DELATESTRYL[®], TESTIM[®], TESTOPEL[®], AVEED[®] and STRIANT[®]), including pulmonary embolism, stroke or other vascular and/or cardiac injuries, and sought compensatory and/or punitive damages, where available.

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 TRT 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 liability or fault by us or any of our subsidiaries.

The MSA established various 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 were to be deposited, established participation requirements and allows for a reduction of the total settlement payment in the event the participation threshold was not met. Auxilium and EPI funded the QSF in November 2019. 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.

The MDL court has been dismissing cases pursuant to the settlement or for failure to comply with court orders. As of April 15, 2020, we were aware of approximately 3 cases that remained pending in the MDL against one or more of our subsidiaries.

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. This lawsuit was 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. In February 2019, the court granted defendants' motion for summary judgment. In November 2019, U.S. Court of Appeals for the Seventh Circuit affirmed.

Although the Group believes it has appropriately estimated the probable total amount of loss associated with testosterone-related 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 overall liability accrual may be required. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 as well as other governmental persons or entities and private plaintiffs in the U.S. and Canada have filed suit against us and/or certain of our subsidiaries, including Endo Health Solutions Inc. (EHSI), Endo Pharmaceuticals Inc. (EPI), Par Pharmaceutical, Inc. (PPI), Par Pharmaceutical Companies, Inc. (PPCI), Endo Generics Holdings, Inc. (EGHI), Vintage Pharmaceuticals, LLC, Generics Bidco I, LLC and DAVA Pharmaceuticals, LLC, and in Canada, Paladin, as well as various other manufacturers, distributors, pharmacies 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 30, 2020, filed cases in the U.S. of which we were aware include, but are not limited to, approximately 20 cases filed by or on behalf of states; approximately 2,780 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 280 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers and approximately 160 cases filed by individuals. Certain of the cases have been filed as putative class actions. The Canadian cases include an action filed by British Columbia on behalf of a proposed class of all federal, provincial and territorial governments and agencies in Canada that paid healthcare, pharmaceutical and treatment costs related to opioids, as well as three additional putative class actions, filed in Ontario, Quebec and British Columbia, seeking relief on behalf of Canadian residents who were prescribed and/or consumed opioid medications.

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. Other cases are pending in various federal or state courts. The cases are at various stages. The first MDL trial, relating to the claims of two Ohio counties (Track One plaintiffs), was set for October 2019 but did not go forward after most defendants settled. EPI, EHSI, PPI and PPCI executed a settlement agreement with the Track One plaintiffs in September 2019 which provided for payments totaling \$10 million and up to \$1 million of VASOSTRICT[®] and/or ADRENALIN[®]. Under the settlement agreement, the Track One plaintiffs may be entitled to additional payments in the event of a comprehensive resolution of government-related opioid claims. The settlement agreement was solely by way of compromise and settlement and was not in any way an admission of liability or fault by us or any of our subsidiaries. The earliest trial is currently scheduled for August 2020; however, trials may occur earlier or later as timing remains uncertain due to the impact of COVID-19 and other factors. Most cases remain at the pleading and/or discovery stage.

The complaints in the cases assert a variety of claims, including but not limited to statutory claims asserting violations of public nuisance, consumer protection, unfair trade practices, racketeering, Medicaid fraud and/or drug dealer liability laws 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 alleged failures to take adequate steps to identify and report suspicious orders and to prevent abuse and diversion. Plaintiffs have generally sought 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.

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. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 the investigations.

In January 2018, EPI received a federal grand jury subpoena from the U.S. District Court for the Southern District of Florida seeking documents and information related to OPANA[®] ER, other oxycodone products and marketing of opioid medications. We are cooperating with the investigation.

In September 2019, EPI, EHSI, PPI and PPCI received subpoenas from the New York State Department of Financial Services seeking documents and information regarding the marketing, sale and distribution of opioid medications in New York. We are providing information responsive to these subpoenas.

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. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In January 2020, EPI and PPI executed a settlement agreement with the state of Oklahoma providing for a payment of approximately \$8.75 million in resolution of potential opioid-related claims. The settlement agreement was solely by way of compromise and settlement and was not in any way an admission of liability or fault by us or any of our subsidiaries.

Generic Drug Pricing Matters

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, EPI, EHSI and/or PPCI, 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, as well as non-class action suits, have generally 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.

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 and other claims allege broader, multiple-product conspiracies. 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.

The MDL court has issued various case management and substantive orders, including orders denying certain motions to dismiss, and discovery is ongoing.

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. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In December 2014, our subsidiary PPI received from the Antitrust Division of the DOJ a federal grand jury subpoena 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 PPCI each received a CID from the U.S. Department of Justice (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. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Other Antitrust Matters

Beginning in November 2013, multiple alleged purchasers of LIDODERM[®] sued our subsidiary EPI and other pharmaceutical companies alleging violations of antitrust law arising out of their settlement of certain patent infringement litigation. The various complaints asserted claims under Sections 1 and 2 of the Sherman Act, state antitrust and consumer protection statutes and/or state common law and sought damages, treble damages, disgorgement of profits, restitution, injunctive relief and attorneys' fees. These cases were consolidated and/or coordinated in a federal MDL in the U.S. District Court for the Northern District of California. The last cases remaining in the MDL were dismissed with prejudice in September 2018, when the court approved EPI's settlements with direct and indirect purchaser classes. Those settlement agreements provided for aggregate payments of approximately \$100 million. Of this total, EPI paid approximately \$60 million in 2018, \$30 million in the first quarter of 2019 and \$10 million in the first quarter of 2020. In September 2019, Blue Cross Blue Shield of Michigan and Blue Care Network of Michigan filed a complaint against EPI and other pharmaceutical companies in the Third Judicial Circuit Court, Wayne County, Michigan, asserting claims substantially similar to those asserted in the MDL. In October 2019, certain defendants removed the case to federal court; in April 2020, the case was remanded back to state court.

Beginning in June 2014, multiple alleged purchasers of OPANA[®] ER sued 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, alleging violations of antitrust law arising out of an agreement reached by EPI and Impax to settle certain patent infringement litigation and EPI's introduction of reformulated OPANA[®] ER. 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. 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 Illinois. The various complaints assert claims under Sections 1 and 2 of the Sherman Act, 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 March 2019, direct and indirect purchaser plaintiffs filed motions for class certification, which remain pending. In April 2020, defendants filed motions for summary judgment.

Beginning in February 2009, the Federal Trade Commission (FTC) and certain private plaintiffs sued our subsidiaries PPCI (since June 2016, EGHI) and/or PPI as well as other pharmaceutical companies alleging violations of antitrust law arising out of the settlement of certain patent litigation concerning the generic version of AndroGel[®] and seeking damages, treble damages, equitable relief and attorneys' fees and costs. The cases were consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Northern District of Georgia. 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. In June 2018, the MDL court granted in part and denied in part various summary judgment and evidentiary motions filed by defendants. In particular, among other things, the court rejected two of the remaining plaintiffs' causation theories and rejected damages claims related to AndroGel[®] 1.62%. In July 2018, the court denied certain plaintiffs' motion for certification of a direct purchaser class. In November 2019, PPI and PPCI entered into settlement agreements with all but one of the remaining plaintiffs in the MDL. The settlement agreements were solely by way of compromise and settlement and were not in any way an admission of liability or fault. Separately, in August 2019, several alleged direct purchasers filed suit in the U.S. District Court for the Eastern District of Pennsylvania asserting claims substantially similar to those asserted in the MDL, as well as additional claims against other defendants relating to other alleged conduct. In January 2020, the U.S. District Court for the Eastern District of Pennsylvania denied defendants' motion to transfer venue to the Northern District of Georgia.

Beginning in February 2018, several alleged indirect purchasers filed proposed class actions against our subsidiary PPI and other pharmaceutical companies alleging violations of antitrust law arising out of the settlement of certain patent litigation concerning the generic version of Zetia[®] (ezetimibe). The various complaints asserted claims under Sections 1 and 2 of the Sherman Act, state antitrust and consumer protection statutes and/or state common law and sought injunctive relief, damages, treble damages, attorneys' fees and costs. In June 2018, these and other related cases, including proposed direct purchaser class actions in which PPI was not named as a defendant, were consolidated and/or coordinated for pretrial proceedings in a federal MDL in the U.S. District Court for the Eastern District of Virginia. In September 2018, the indirect purchaser plaintiffs dismissed their claims against PPI without prejudice. In June and July 2019, the MDL court granted the direct purchaser plaintiffs and certain retailer plaintiffs leave to file amended complaints adding PPI as a defendant. In July 2019, PPI entered into settlement agreements with both the direct purchaser plaintiffs and the retailer plaintiffs. The direct purchaser settlement was subject to court approval, which was granted in March 2020. The settlement agreements were solely by way of compromise and settlement, were not in any way an admission of liability or fault and involved no monetary payment.

Beginning in May 2018, multiple complaints were filed in the U.S. District Court for the Southern District of New York against PPI, EPI and/or us, as well as other pharmaceutical companies, alleging violations of antitrust law arising out of the settlement of certain patent litigation concerning the generic version of Exforge[®] (amlodipine/valsartan). Some cases were filed on behalf of putative classes of direct and indirect purchasers; others are non-class action suits. The various complaints assert claims under Sections 1 and 2 of the Sherman Act, state antitrust and consumer protection statutes and/or state common law. Plaintiffs generally 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, which was granted in August 2019. The cases are currently in discovery.

Beginning in August 2019, multiple complaints were filed in the U.S. District Court for the Southern District of New York against PPI and other pharmaceutical companies alleging violations of antitrust law arising out of the settlement of certain patent litigation concerning generic versions of Seroquel XR[®] (extended release quetiapine fumarate). The claims against PPI are based on allegations that PPI entered into an exclusive acquisition and license agreement with Handa Pharmaceuticals, LLC (Handa) in 2012 pursuant to which Handa assigned to PPI certain rights under a prior settlement agreement between Handa and AstraZeneca resolving certain patent litigation. Some cases were filed on behalf of putative classes of direct and indirect purchasers; others are non-class action suits. The various complaints assert claims under Sections 1 and 2 of the Sherman Act, state antitrust and consumer protection statutes and/or state common law. Plaintiffs generally seek damages, treble damages, equitable relief and attorneys' fees and costs. In October 2019, the defendants filed various motions to dismiss and, in the alternative, moved to transfer the litigation to the U.S. District Court for the District of Delaware.

To the extent unresolved, 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. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In February 2015, EGHI and affiliates received a CID from the Office of the Attorney General for the state of Alaska seeking documents and information regarding EGHI's settlement of AndroGel[®] patent litigation as well as documents produced in the aforementioned litigation filed by the FTC. Also in February 2015, EHSI received a CID from Alaska's Office of the Attorney General seeking production of certain documents and information concerning agreements with Actavis and Impax settling OPANA[®] ER patent litigation. We are cooperating with the investigations.

In July 2019, EPI received a CID from the FTC seeking documents and information regarding oxycodone ER and EPI's settlement of a contract dispute with Impax (now Amneal) in August 2017. 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 additional losses that could be incurred. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Securities Litigation

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. The complaint alleged violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 against us, certain of our current and former directors and officers, and the underwriters who participated in the offering, based on certain disclosures about Endo's generics business. In June 2019, the parties entered into a settlement providing for, among other things, a \$50 million payment to the investor class in exchange for a release of their claims. In December 2019, the court denied a petition to intervene filed by the lead plaintiff in the *Pelletier* litigation described below, and granted final approval of the settlement. In December 2019, the putative intervenor appealed the denial of its petition to intervene and the final approval order to Pennsylvania Superior Court. That appeal remains pending. As a result of the settlement, during the first quarter of 2019, the Group recorded an increase of approximately \$50 million to its accrual for loss contingencies. As the Group's insurers agreed to fund the settlement, the Group also recorded a corresponding insurance receivable of approximately \$50 million during the first quarter of 2019, which was recorded as Prepaid expenses and other current assets in the Consolidated Balance Sheet. The Group's insurers funded the settlement during the third quarter of 2019, resulting in corresponding decreases to the Group's accrual for loss contingencies and insurance receivable.

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 sought class certification, declaratory relief, damages, interest and costs based on alleged violations of the Ontario Securities Act arising out of alleged 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, based on our decision to voluntarily remove reformulated OPANA[®] ER from the market. In April 2020, the parties reached a settlement in principle, which will be subject to court approval. The amount of the settlement is not material to the Group and is expected to be funded by the Group's insurers.

In August 2017, an alleged individual shareholder filed a putative class action entitled *Bier v. Endo International plc* in the U.S. District Court for the Eastern District of Pennsylvania, alleging violations of Sections 10(b) and 20(a) of the Exchange Act against us, EHSI and certain of our current and former directors and officers, based on our decision to voluntarily remove reformulated OPANA[®] ER from the market. In December 2017, the court appointed SEB Investment Management AB lead plaintiff in the action. In August 2019, the parties entered into a settlement providing for, among other things, a payment of \$82.5 million to the investor class in exchange for a release of their claims. The settlement received preliminary court approval in September 2019 and final approval in December 2019. As a result of the settlement, during the second quarter of 2019, the Group recorded an increase of approximately \$82.5 million to its accrual for loss contingencies. As the Group's insurers agreed to fund the settlement, the Group also recorded a corresponding insurance receivable of approximately \$82.5 million during the second quarter of 2019, which was recorded as Prepaid expenses and other current assets in the Consolidated Balance Sheet. With respect to this settlement, the Group's insurers funded \$20.0 million during the third quarter of 2019 and the remainder in October 2019, resulting in corresponding decreases to the Group's accrual for loss contingencies and insurance receivable.

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' and Retirement Board Employees' Annuity Benefit Fund of Chicago lead plaintiff in the action. In September 2018, the defendants filed a motion to dismiss, which the court granted in part and denied in part in February 2020. In particular, the court granted the motion and dismissed the claims with prejudice insofar as they were based on an alleged price-fixing conspiracy; the court otherwise denied the motion to dismiss, allowing other aspects of lead plaintiff's claims to proceed.

To the extent unresolved, 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. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

VASOSTRICT® Related Matters

In July 2016, Fresenius Kabi USA, LLC (Fresenius) sued our subsidiaries PPCI and Par Sterile Products, LLC (PSP LLC) in the U.S. District Court for the District of New Jersey alleging an anticompetitive scheme to exclude competition for PPCI's VASOSTRICT®, a vasopressin-based cardiopulmonary drug. In particular, Fresenius alleged violations of Sections 1 and 2 of the Sherman Antitrust Act, as well as state antitrust and common law, based on assertions that our subsidiaries entered into exclusive supply agreements with one or more active pharmaceutical ingredient (API) manufacturers and that, as a result, Fresenius could not obtain vasopressin API in order to file an Abbreviated New Drug Application (ANDA) to obtain U.S. Food and Drug Administration (FDA) approval for its own vasopressin product. Fresenius sought actual, treble and punitive damages, attorneys' fees and costs and injunctive relief. In February 2020, the court granted our subsidiaries' motion for summary judgment on all claims and denied Fresenius's cross-motion for partial summary judgment. In March 2020, Fresenius filed a notice of appeal to the U.S. Court of Appeals for the Third Circuit.

In August 2017, our subsidiaries PPI and PSP LLC filed a complaint for actual, exemplary and punitive damages, injunctive relief and other relief against QuVa Pharma, Inc. (QuVa), Stuart Hinchey, 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®. In November 2017, we filed a motion for preliminary injunction seeking various forms of relief. 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. In May 2018, defendants filed a notice of appeal to the Third Circuit Court of Appeals indicating intent to appeal the court's preliminary injunction. In February 2019, the defendants 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. 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 September 2019, following the decision in *Athenex Inc. v. Azar*, No. 19-cv-00603, 2019 WL 3501811 (D.D.C. Aug. 1, 2019), which upheld the FDA's determination that there is no clinical need for outsourcing facilities to compound drugs using bulk vasopressin, the parties submitted a proposed consent order to the district court agreeing to a lifting of the preliminary injunction against QuVa but reserving PPI and PSP LLC's right to seek return or reduction of the bond. In January 2020, the court granted our motion to dismiss the defendants' counterclaims and ordered the preliminary injunction lifted while the bond remains in place pending an adjudication on the merits. In March 2020, we filed a motion for partial summary judgment on the merits of PPI and PSP LLC's breach of contract claims.

Beginning in April 2018, PSP LLC and PPI received notice letters from Eagle Pharmaceuticals, Inc., Sandoz, Inc., Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, American Regent, Fresenius, Dr. Reddy's Laboratories, Inc. and Aurobindo Pharma Limited advising of the filing by such companies of ANDAs/New Drug Applications (NDAs) for generic versions of VASOSTRICT® (vasopressin IV solution (infusion)) 20 units/ml and/or 200 units/10 ml. Beginning in May 2018, PSP LLC, PPI and Endo Par Innovation Company, LLC (EPIC) filed lawsuits against Eagle Pharmaceuticals, Inc., Sandoz, Inc., Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, American Regent and Fresenius in the U.S. District Court for the District of Delaware or New Jersey within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. The earliest trial is presently scheduled for January 2021; however, a trial may occur earlier or later as timing remains uncertain due to the impact of COVID-19 and other factors.

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. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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.

Contractual Obligations. The following table lists our enforceable and legally binding noncancelable obligations as of December 31, 2019.

	Payment Due by Period (in thousands)						
	Total	2020	2021	2022	2023	2024	Thereafter
Long-term debt obligations (1)	\$ 8,470,678	\$ 34,150	\$ 34,150	\$ 247,723	\$ 1,684,430	\$ 3,770,225	\$ 2,700,000
Interest expense (2)	2,542,549	525,976	523,927	510,591	457,330	265,400	259,325
Finance lease obligations (3)	52,216	7,446	7,593	7,743	7,897	8,054	13,483
Operating lease obligations (3)	70,578	14,103	13,262	12,688	10,017	5,176	15,332
Purchase obligations (4)	37,471	20,319	11,927	818	941	632	2,834
Mesh-related product liability settlements (5)	54,769	54,769	—	—	—	—	—
Other obligations and commitments (6)	1,602	1,602	—	—	—	—	—
Total (7)	<u>\$ 11,229,863</u>	<u>\$ 658,365</u>	<u>\$ 590,859</u>	<u>\$ 779,563</u>	<u>\$ 2,160,615</u>	<u>\$ 4,049,487</u>	<u>\$ 2,990,974</u>

- (1) Includes minimum cash payments related to principal associated with our indebtedness as of December 31, 2019. A discussion of such indebtedness is included above under the caption "Indebtedness." The amounts in this table do not reflect any potential early or accelerated principal payments such as the potential payments described in Note 13. Debt.
- (2) These amounts represent future cash interest payments related to our indebtedness as of December 31, 2019 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, 2019, plus the specified margin in the associated debt agreements for each period presented.
- (3) Refer to Note 8. Leases for additional information about our leases. We have entered into agreements to sublease certain properties. Most significantly, we sublease 140,000 square feet of our Malvern, Pennsylvania facility and substantially all of our Chesterbrook, Pennsylvania facility. As of December 31, 2019, we expect to receive approximately \$24.7 million (2018: \$29.7 million) in future minimum rental payments over the remaining terms of the Malvern and Chesterbrook subleases from 2020 to 2024. Amounts of expected sublease income are not reflected in the table above.
- (4) Purchase obligations are enforceable and legally binding obligations for purchases of goods and services, including minimum stock contracts.
- (5) 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.
- (6) Other obligations and commitments relate to any agreements to purchase third-party assets, products and services and other minimum royalty obligations.
- (7) Total generally does not include contractual obligations already included in current liabilities on our Consolidated Balance Sheet, except for amounts related to the current portion of long-term debt, accrued interest, current 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, 2019, 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 19. 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, if any. Therefore, our liability has been excluded from the above contractual obligations table.

NOTE 15. OTHER COMPREHENSIVE PROFIT (LOSS)

There were no significant tax effects allocated to any component of Other comprehensive income / (loss) for the years ended December 31, 2019 and 2018. Substantially all of the Group’s Accumulated other comprehensive income (loss) balances at December 31, 2019 and December 31, 2018 consist of Foreign currency translation gain / (loss).

NOTE 16. SHARE CAPITAL

The Group has 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.

Effects of Changes in Accounting Principles

As further discussed in Note 2. Summary of Significant Accounting Policies, the Group adopted ASC 606 on January 1, 2018. This adoption resulted in a net increase of \$3.1 million to the Group’s Profit and loss account at January 1, 2018.

As further discussed in Note 2. Summary of Significant Accounting Policies, the Group adopted ASC 842 on January 1, 2019. This adoption resulted in a net increase of \$4.6 million to the Group’s Accumulated deficit at January 1, 2019.

Share Capital consists of the following for the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
Authorized:		
4,000,000 Euro deferred shares of \$0.01 par value (4,000,000 issued and outstanding)	\$ 40	\$ 40
1,000,000,000 ordinary shares of \$0.0001 par value (226,802,609 issued and outstanding)	100	100
Total share capital.....	<u>\$ 140</u>	<u>\$ 140</u>
Allotted, called-up and fully paid equity:		
BALANCE, JANUARY 01, 2018		\$ 70
Other		<u>(2)</u>
BALANCE, DECEMBER 31, 2018		\$ 68
Other		—
BALANCE, DECEMBER 31, 2019		<u>\$ 68</u>

Share Repurchase Program

Pursuant to Article 11 of the Group's Articles of Association, the Group has broad shareholder authority to conduct ordinary share repurchases by way of redemptions. The Group's authority to repurchase ordinary shares is subject to legal limitations and the existence of sufficient distributable reserves. For example, the Companies Act requires Irish companies to have distributable reserves equal to or greater than the amount of any proposed ordinary share repurchase amount. Unless we are able to generate sufficient distributable reserves or create distributable reserves by reducing our share premium account, we will not be able to repurchase our ordinary shares. As permitted by Irish Law and the Group's Articles of Association, any ordinary shares redeemed shall be cancelled upon redemption.

The Board has approved the 2015 Share Buyback Program that authorizes the Group to redeem, in the aggregate, \$2.5 billion of its outstanding ordinary shares. To date, the Group has redeemed and cancelled approximately 4.4 million of its ordinary shares under the 2015 Share Buyback Program for \$250.0 million, not including related fees.

NOTE 17. SHARE-BASED COMPENSATION

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 2018 and 2019. 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 Compensation Committee of the Board 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 against targets covering three independent successive one-year performance periods, 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.

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 Consolidated Balance Sheet. On October 1, 2018, the Compensation Committee of the Board 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 17. 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, 2019, approximately 7.7 million ordinary shares were reserved for future grants under the 2015 Plan. As of December 31, 2019, 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, 2019 and 2018 (in thousands).

	2019	2018
Selling, general and administrative expenses.....	\$ 44,159	\$ 44,454
Research and development expenses	4,501	2,251
Cost of sales	10,482	7,366
Total share-based compensation expense	<u>\$ 59,142</u>	<u>\$ 54,071</u>

As of December 31, 2019, 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, 2019 amounted to \$48.3 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 generally 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, 2019 and 2018 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (1)
Outstanding as of January 1, 2018	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		
Exercised	(557)	\$ 7.55		
Forfeited.....	(125,739)	\$ 14.38		
Expired.....	(665,883)	\$ 40.37		
Outstanding as of December 31, 2019	7,280,539	\$ 18.93	6.30	\$ —
Vested and expected to vest as of December 31, 2019	7,212,334	\$ 19.00	6.29	\$ —
Exercisable as of December 31, 2019	5,003,163	\$ 21.60	6.07	\$ —

(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, 2019 is from \$7.55 to \$86.54 (2018: \$7.55 to \$89.68).

The total intrinsic values of options exercised during the years ended December 31, 2019 and 2018 were less than \$0.1 million and \$0.6 million, respectively. No tax benefits from stock option exercises were realized during the years ended December 31, 2019 and 2018. The weighted average grant-date fair values of the stock options granted during the year ended December 31, 2018 was \$3.97 per option, respectively, determined using the following weighted average assumptions:

	2018
Expected term (years)	4.0
Risk-free interest rate	2.7%
Dividend yield.....	—
Expected volatility	63%

As of December 31, 2019, the weighted average remaining requisite service period of non-vested stock options was 0.9 years (2018: 1.7) and the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$3.1 million.

Restricted Stock Units and Performance Share Units

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.

PSUs awarded in 2019 and 2018 were based upon two discrete measures: relative total shareholder return (TSR) and an adjusted free cash flow performance metric (FCF), each accounting for 50% of the PSU awards upon issuance. TSR performance is measured against the three-year TSR of a custom index of companies. For PSUs awarded in 2019, FCF performance is measured against a target covering a single three-year performance period, which is generally established at the grant date. For PSUs awarded in 2018, FCF performance is measured against targets covering three independent successive one-year performance periods, which are generally established for each performance period during the first quarter of that calendar year. Upon the completion of the three-year performance period, the PSUs vest and the actual number of shares awarded is adjusted to between zero and 200% of the target award amount based upon the performance criteria described above. 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 is considered a market condition under applicable authoritative guidance, while FCF is considered performance condition.

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, 2019 and 2018 is presented below:

	Number of Shares	Aggregate Intrinsic Value (1)
Non-vested as of January 1, 2018	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	
Granted	6,687,695	
Forfeited.....	(918,425)	
Vested.....	(3,872,453)	
Non-vested as of December 31, 2019	12,916,289	\$ 60,577,395
Vested and expected to vest as of December 31, 2019	12,098,438	\$ 56,741,674

(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, 2019, the weighted average remaining requisite service period of the units presented in the table above was 1.6 years (2018: 1.9 years) and the corresponding total remaining unrecognized compensation cost amounted to \$39.4 million in the case of RSUs and LTCI awards and \$5.8 million in the case of PSUs. The weighted average grant-date fair value of the units granted during the years ended December 31, 2019 and 2018 was \$7.72 and \$6.88 per unit, respectively.

NOTE 18. OTHER PROFIT, NET

The components of Other expense (profit), net for the years ended December 31, 2019 and 2018 are as follows (in thousands):

	2019	2018
Net gain on sale of business and other assets (1)	\$ (6,367)	\$ (45,155)
Foreign currency loss (gain), net (2)	5,247	(3,762)
Net loss from our investments in the equity of other companies (3).....	2,346	3,444
Other miscellaneous, net (4).....	15,451	(6,480)
Other expense (profit), net.....	<u>\$ 16,677</u>	<u>\$ (51,953)</u>

- (1) Amounts in 2018 include a \$12.5 million gain on the sale of the Group's Huntsville, Alabama facilities, as further discussed in Note 4. Restructuring. The remaining amounts primarily relate to the sales of various ANDAs.
- (2) Amounts relate to the remeasurement of the Group's foreign currency denominated assets and liabilities.
- (3) Amounts relate to the income statement impacts of our investments in the equity of other companies, including investments accounted for under the equity method.
- (4) Amounts in 2019 primarily relate to \$17.5 million of contract termination costs incurred as a result of certain product discontinuation activities in our International Pharmaceuticals segment.

NOTE 19. 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, including the reduction of the U.S. statutory federal corporate income tax rate from 35% to 21% effective January 1, 2018. The TCJA also 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 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 in the Income tax expense (benefit) line. The Group has completed its accounting for the tax effects of the TCJA in accordance with Staff Accounting Bulletin 118. There were no significant subsequent adjustments to the provisional amounts recorded.

Loss from continuing operations before income tax

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, 2019 and 2018 are as follows (in thousands):

	2019	2018
U.S.	\$ (670,724)	\$ (1,342,860)
International	343,320	404,028
Total (loss) profit from continuing operations before income tax.....	<u>\$ (327,404)</u>	<u>\$ (938,832)</u>

Income tax from continuing operations consists of the following for the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
Current:		
U.S. Federal	\$ 15,317	\$ 6,236
U.S. State	(3,002)	2,864
International	8,926	8,278
Total current income tax	\$ 21,241	\$ 17,378
Deferred:		
U.S. Federal	\$ (515)	\$ 10,084
U.S. State	(482)	(778)
International	(4,564)	(3,749)
Total deferred income tax	\$ (5,561)	\$ 5,557
Total income tax	\$ 15,680	\$ 22,935

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, 2019 and 2018 is as follows (in thousands):

	2019	2018
Notional U.S. federal income tax provision at the statutory rate	\$ (72,430)	\$ (197,155)
State income tax, net of federal benefit	(4,455)	494
U.S. tax reform impact	—	5,664
Uncertain tax positions	43,273	46,317
Residual tax on non-U.S. net earnings	(67,987)	(638,724)
Non-deductible goodwill impairment	27,493	109,189
Change in valuation allowance	30,123	748,562
Intra-entity transfers of assets	—	(63,335)
Base erosion minimum tax	13,662	—
Non-deductible expenses	21,299	3,446
Executive compensation limitation	4,547	5,955
Other	20,155	2,522
Income tax	\$ 15,680	\$ 22,935

The income tax expense in 2019 primarily related to accrued interest on uncertain tax positions. The income tax expense in 2018 primarily related to the establishment of a valuation allowance against certain U.S. deferred tax assets.

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, 2019 and 2018 are as follows (in thousands):

	December 31, 2019	December 31, 2018
Deferred tax assets:		
Accrued expenses and customer allowances	\$ 112,489	\$ 185,910
Deferred interest expense.....	317,997	240,736
Fixed assets and intangible assets	598,730	604,385
Loss on capital assets.....	61,971	62,033
Net operating loss carryforward.....	9,743,763	8,751,544
Other	89,501	65,266
Research and development and other tax credit carryforwards	16,620	9,551
Total gross deferred income tax assets	<u>\$ 10,941,071</u>	<u>\$ 9,919,425</u>
Deferred tax liabilities:		
Other	\$ (10,086)	\$ (1,965)
Outside basis difference.....	—	(73,652)
Intercompany notes.....	(1,131,537)	—
Total gross deferred income tax liabilities.....	<u>\$ (1,141,623)</u>	<u>\$ (75,617)</u>
Valuation allowance.....	(9,828,959)	(9,877,617)
Net deferred income tax liability.....	<u>\$ (29,511)</u>	<u>\$ (33,809)</u>

At December 31, 2019, the Group had the following significant deferred tax assets for tax credits, net operating and capital loss carryforwards, net of unrecognized tax benefits (in thousands):

Jurisdiction	Amount	Begin to Expire
Ireland	\$ 16,862	Indefinite
Luxembourg	\$ 9,336,611	2034
U.S.:		
Federal-ordinary losses	\$ 200,671	2021
Federal-capital losses.....	\$ 34,740	2020
Federal-tax credits	\$ 7,305	2026
State-ordinary losses.....	\$ 186,211	2020
State-capital losses.....	\$ 26,459	2026
State-tax credits	\$ 6,643	2020

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 whether the existing deferred tax assets will be realized.

The Group has recorded a valuation allowance against certain jurisdictional net operating loss carryforwards and other tax attributes. As of December 31, 2019 and 2018, the total valuation allowance was \$9,829.0 million and \$9,877.6 million, respectively. During the year ended December 31, 2019, the Group decreased its valuation allowance by \$48.7 million, which was primarily driven by statutory rate changes in Luxembourg. During the year ended December 31, 2018, the Group increased its valuation allowance by \$1,814.6 million, which 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.

At December 31, 2019, the Group had the following significant valuation allowances (in thousands):

Jurisdiction	December 31, 2019
Ireland	\$ 189,581
Luxembourg	\$ 8,205,074
U.S.	\$ 1,430,762

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. As of December 31, 2019, certain subsidiaries had approximately \$1,092.0 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. The Group believes it has appropriately established reserves 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, including 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, 2019, the Group had total unrecognized income tax benefits (UTBs) of \$530.2 million. If recognized in future years, \$320.3 million of such amounts would impact the income tax provision and effective tax rate. As of December 31, 2018, the Group had total UTBs of \$479.4 million. If recognized in future years, \$304.3 million of such amounts would have impacted the income tax provision and effective tax rate. The following table summarizes the activity related to UTBs during the years ended December 31, 2019 and 2018 (in thousands):

	Unrecognized Tax Benefit Federal, State, and Foreign Tax
UTB Balance at January 1, 2018.....	\$ 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.....	<u>\$ 451,690</u>
Gross additions for current year positions	35,766
Gross reductions for prior period positions.....	(2,377)
Gross additions for prior period positions.....	880
Decrease due to lapse of statute of limitations.....	(1,006)
Currency translation adjustment	1,528
UTB Balance at December 31, 2019.....	<u>\$ 486,481</u>
Accrued interest and penalties	43,710
Total UTB balance including accrued interest and penalties.....	<u>\$ 530,191</u>

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, 2019 and 2018, \$43.7 million and \$27.7 million, respectively, of corresponding accrued interest and penalties is included in the Consolidated Balance Sheet, all of which is recorded in income taxes.

During the years ended December 31, 2019 and 2018, we recognized expense of \$13.8 million and \$8.6 million, respectively. The expense is primarily related to interest. The current portion of our UTB liability of \$6.8 million is included in our Consolidated Balance Sheet as Accounts payable and accrued expenses. The noncurrent 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 IRS.

It is expected that the amount of UTBs will change during the next twelve months; however, the Group does not currently anticipate any adjustments that would lead to a material impact on our results of operations or our financial position.

As of December 31, 2019, we may be subject to examination in the following major tax jurisdictions:

Jurisdiction	Open Years
Canada.....	2013 through 2019
India.....	2012 through 2019
Ireland	2014 through 2019
Luxembourg	2014 through 2019
U.S. - federal, state and local.....	2006 through 2019

NOTE 20. 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, 2019 and 2018 (in thousands):

	<u>2019</u>	<u>2,018</u>
Numerator:		
Loss from continuing operations	\$ (343,084)	\$ (961,767)
Loss from discontinued operations, net of tax	(92,052)	(69,702)
Net loss	<u>\$ (435,136)</u>	<u>\$ (1,031,469)</u>
Denominator:		
For basic per share data—weighted average shares.....	226,050	223,960
Dilutive effect of ordinary share equivalents.....	—	—
For diluted per share data—weighted average shares.....	<u>226,050</u>	<u>223,960</u>

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 effect 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 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, 2019 and 2018 because their effect would have been anti-dilutive, as the Group was in a loss position.

NOTE 21. 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 \$7.4 million and \$6.4 million for the years ended December 31, 2019 and 2018, 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 22. DEBTORS

The components of Debtors for the years ended December 31, 2019 and 2018 (in thousands) were as follows:

	2019	2018
<i>Amounts falling due within one year:</i>		
Trade debtors.....	\$ 467,953	\$ 470,570
Prepayments and other debtors	40,845	106,139
Income taxes receivable	47,567	39,781
	<u>\$ 556,365</u>	<u>\$ 616,490</u>
<i>Amounts falling due after more than one year:</i>		
Deferred tax asset.....	\$ 2,192	\$ 678
Other debtors.....	78,101	66,993
	<u>\$ 80,293</u>	<u>\$ 67,671</u>

NOTE 23. PROVISIONS AND CREDITORS

The components of Provisions and Creditors for the years ended December 31, 2019 and 2018 (in thousands) were as follows:

	Note	2019	2018
<i>Provisions for liabilities:</i>			
<i>Amounts falling due within one year:</i>			
Returns and allowances, rebates, chargebacks	23 ...	\$ 336,898	\$ 384,777
Acquisition-related contingent consideration—short-term	6	6,534	36,514
		<u>\$ 343,432</u>	<u>\$ 421,291</u>
<i>Amounts falling due after more than one year:</i>			
Acquisition-related contingent consideration—long-term	6	23,123	80,189
		<u>\$ 366,555</u>	<u>\$ 501,480</u>
<i>Creditors:</i>			
<i>Amounts falling due within one year:</i>			
Trade accounts payable		\$ 101,532	\$ 96,024
Accrued expenses.....		454,985	491,885
Current portion of legal settlement accrual.....	14 ...	525,505	955,085
Income taxes payable	19 ...	2,422	1,661
		<u>\$ 1,084,444</u>	<u>\$ 1,544,655</u>
<i>Amounts falling due after more than one year:</i>			
Deferred income taxes	19 ...	31,703	34,487
Income taxes payable.....	19 ...	288,231	261,109
Other creditors		44,527	80,526
		<u>\$ 364,461</u>	<u>\$ 376,122</u>
		<u>\$ 1,448,905</u>	<u>\$ 1,920,777</u>

The following table summarizes changes in the ending balances for our product sales provisions from December 31, 2019 and 2018 (in thousands):

	Returns and Allowances	Rebates	Chargebacks	Total
Balance, December 31, 2018.....	\$ 236,946	\$ 144,247	\$ 3,584	\$ 384,777
Current year provision.....	89,380	319,815	4,789	413,984
Prior year provision.....	(4,035)	(3,972)	111	(7,896)
Payments or credits	(116,044)	(331,647)	(6,276)	(453,967)
Balance, December 31, 2019.....	\$ 206,247	\$ 128,443	\$ 2,208	\$ 336,898

NOTE 24. CAPITAL EXPENDITURE COMMITMENTS

The directors have authorized the Group to spend \$82 million for capital expenditures in the year ended December 31, 2020.

NOTE 25. 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 29. 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 27. Directors' Remuneration.

NOTE 26. EMPLOYEES

The average number of persons employed by the Group for the years ended December 31, 2019 and 2018 were as follows:

	2019	2018
Manufacturing	1,705	1,655
Research and development	394	394
Selling, general and administrative	952	897
Total employees.....	3,051	2,946

Employee costs for the years ended December 31, 2019 and 2018 (in thousands) were as follows:

	2019	2018
Wages and salaries.....	\$ 291,148	\$ 352,752
Benefits (1).....	56,580	77,607
Share-based compensation	59,142	54,071
Total employee cost.....	\$ 406,870	\$ 484,430

(1) Benefits include social security costs, employer paid payroll taxes and other employee benefits paid by the Group.

NOTE 27. DIRECTORS' REMUNERATION

Directors' remuneration set forth in the table below. Mr. Paul Campanelli, the Chief Executive Officer, was not provided additional compensation for his service as a director. The amounts below include compensation for Mr. Paul Campanelli as Chief Executive Officer and compensation for all non-employee directors in their capacity as such. There were no contributions made to retirement benefit schemes or compensation paid for loss of office to non-executive directors during the periods presented.

	2019	2018
Emoluments.....	\$ 5,354	\$ 3,543
Benefits under long-term incentive schemes.....	\$ 5,236	\$ 4,262
Contributions to retirement benefit schemes:		
Defined contribution.....	\$ —	\$ —
Defined benefit.....	—	—
	\$ —	\$ —
Compensation for loss of office paid by the company and other termination payments.....	\$ —	\$ —

NOTE 28. AUDITORS' REMUNERATION

PricewaterhouseCoopers LLP served as the Group's independent registered public accounting firm for the years ended December 31, 2019 and 2018. The table below summarizes the aggregate fees for services PricewaterhouseCoopers LLP provided during years 2019 and 2018, respectively.

	2019	2018
Audit fees (1).....	\$ 6,637	\$ 7,781
Audit-related fees (2).....	538	626
Tax fees (3).....	1,308	3,617
All other fees (4).....	106	237
Total auditors' remuneration.....	\$ 8,589	\$ 12,261

(1) Fees for audit services in 2019 and 2018 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 2019 and 2018 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 2019 and 2018 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 2019 principally includes compliance advisory services and subscriptions to knowledge tools. All other fees in 2018 principally includes subscriptions to knowledge tools.

NOTE 29. 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 Ownership
Actient Pharmaceuticals LLC	Delaware	Indirect	100%
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 Designated Activity Company	Ireland	Direct	100%
Endo Eurofin Unlimited Company	Ireland	Indirect	100%
Endo Finance II Unlimited Company	Ireland	Indirect	100%
Endo Finance IV Unlimited Company	Ireland	Indirect	100%
Endo Finance Unlimited Company	Ireland	Indirect	100%
Endo Finance LLC	Delaware	Indirect	100%
Endo Finance Operations LLC	Delaware	Indirect	100%
Endo Global Biologics Limited	Ireland	Indirect	100%
Endo Health Solutions Inc.	Delaware	Indirect	100%
Endo Ireland Finance Unlimited Company	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 Pharmaceuticals Valera Inc.	Delaware	Indirect	100%
Endo TopFin Limited	Ireland	Indirect	100%
Endo U.S. Inc.	Delaware	Indirect	100%
Endo U.S. Finance LLC	Delaware	Indirect	100%
Endo US Holdings Luxembourg I 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%
Luxembourg Endo Specialty Pharmaceuticals Holding I 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%

NOTE 30. SUBSEQUENT EVENTS

Subsequent events have been evaluated through May 07, 2020 the date this report is approved by the Audit Committee of the Board of Directors and the Board of Directors.

COVID-19

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China. In March 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. Many countries and localities have announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, suspending all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing shelter-in-place orders (subject to limited exceptions). We are closely monitoring the impact of COVID-19 on all aspects of our business, the pharmaceutical industry and the economy as a whole, including how it has and will continue to impact our workforce, our customers and the patients they serve, our manufacturing and supply chain operations, our R&D programs and regulatory approval processes and our liquidity and access to capital. In addition, we have implemented plans intended to limit the impact of COVID-19 on our business so that we can continue to produce the critical care medicines that hospitals and healthcare providers need to treat patients, including those with COVID-19. The extent to which COVID-19 will impact our business, financial position and operating results cannot be predicted with certainty due to numerous uncertainties related to COVID-19, but any such impact could be material. The Group has formed a judgment at the time of approving the financial statements that there is a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future. In arriving at this conclusion, the Group has taken account of all available information about the future, including risks and uncertainties related to COVID-19, current and anticipated trading performance and 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's financial statements. Other than disclosed in these financial statements, there is no material impact arising from COVID-19 at the date of the approval of the financial statements in respect of assets and liabilities which were carried as at December 31, 2019.

On March 27, 2020, the CARES Act was enacted by the U.S. government in response to the COVID-19 pandemic. The CARES Act, among other things, permits net operating loss (NOL) carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. In the first quarter of 2020, the Group has recorded a discrete tax benefit in continuing operations of \$137.3 million as a result of the change in the NOL carryback period. This tax benefit is a non-recognized subsequent event for the year ended December 31, 2019.

Impairments

As a result of certain business decisions that occurred during the first quarter of 2020, we tested the goodwill of our Paladin reporting unit for impairment as of March 31, 2020. The fair value of the reporting unit was estimated using an income approach that utilized a discounted cash flow model. The discount rate utilized in this test was 9.5%. This goodwill impairment test resulted in a pre-tax non-cash goodwill impairment charge of \$32.8 million during the three months ended March 31, 2020, representing the remaining carrying amount. This impairment was primarily attributable to portfolio decisions and updated market expectations during the quarter.

In addition, we recorded \$63.8 million of pre-tax non-cash asset impairment charges during the three months ended March 31, 2020 related primarily to certain developed technology intangible assets that were tested for impairment following changes in market conditions and certain other factors impacting recoverability.

These impairment charges are non-recognized subsequent events for the year ended December 31, 2019.

Legal Accruals

Subsequent to December 31, 2019, adjustments were made to recognize litigation charges related to probable and estimable damages for matters that existed at December 31, 2019. The following adjustments were made to balances previously reported in the Consolidated Statements of Operations included in Endo International plc's Annual Report on Form 10-K (10-K) filed with the Securities and Exchange Commission on February 26, 2020.

(in thousands)	As reported in Form 10-K	Litigation adjustment	Adjusted balance
Litigation-related and other contingencies, net	\$ 11,211	\$ (17,500)	\$ (6,289)
Discontinued Operations, Net of Tax	(62,052)	(30,000)	(92,052)

The following adjustments were made to balances previously reported in the Consolidated Balance Sheets included in Endo International plc's Annual Report on Form 10-K (10-K) filed with the Securities and Exchange Commission on February 26, 2020.

(in thousands)	As reported in Form 10-K	Litigation adjustment	Adjusted balance
Current portion of legal settlement accrual	\$ 513,005	\$ 12,500	\$ 525,505

NOTE 31. APPROVAL OF THE FINANCIAL STATEMENTS

The financial statements were approved by the directors on May 07, 2020.

ENDO INTERNATIONAL PLC
COMPANY RECONCILIATION OF SHAREHOLDERS' FUNDS
FOR THE YEARS ENDED DECEMBER 31, 2019
(In thousands)

	Share Capital Presented as Equity	Share Premium	Profit and Loss Account	Other Reserves	Total Equity
BALANCE, January 1, 2018.....	\$ 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
Net loss.....	—	—	(759,901)	—	(759,901)
Share-based payment activity.....	—	—	—	59,142	59,142
Option exercises	—	—	—	—	—
LTCI modification.....	—	—	—	—	—
Receipt of Endo International's shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards .	—	—	(10,156)	—	(10,156)
Other	—	(109)	—	—	(109)
BALANCE, DECEMBER 31, 2019	\$ 68	\$ 6,156,265	\$ (5,292,595)	\$ 346,582	\$ 1,210,320

ENDO INTERNATIONAL PLC
COMPANY BALANCE SHEET
DECEMBER 31, 2019
(In thousands)

	Note	December 31, 2019	December 31, 2018
ASSETS			
<i>Financial Fixed Assets</i>			
Investment in subsidiaries	3	\$ 1,354,359	\$ 1,989,676
<i>Current Assets</i>			
Debtors - Prepayments and other debtors.....		7,791	4,604
Debtors - Amounts due from subsidiaries	4	20,598	52,191
Cash at bank and in hand		4,419	6,863
TOTAL ASSETS		<u>\$ 1,387,167</u>	<u>\$ 2,053,334</u>
EQUITY AND LIABILITIES			
<i>Capital and Reserves</i>			
Called up share capital presented as equity, \$0.01 par value Euro deferred shares.....	7	\$ 46	\$ 46
Called up share capital presented as equity, \$0.0001 par value ordinary shares	7	22	22
Share premium account.....	7	6,156,265	6,156,374
Other reserves	7	346,582	287,440
Profit and loss account		(5,292,595)	(4,522,538)
Total equity		<u>\$ 1,210,320</u>	<u>\$ 1,921,344</u>
<i>Creditors (amounts falling due within one year)</i>			
Intercompany loan payable	5	\$ 114,921	\$ 97,675
Amounts due to subsidiaries	6	49,887	26,855
Accruals and other creditors.....		12,039	7,460
Total for creditors		<u>\$ 176,847</u>	<u>\$ 131,990</u>
TOTAL EQUITY AND LIABILITIES		<u>\$ 1,387,167</u>	<u>\$ 2,053,334</u>

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 May 07, 2020 and signed on its behalf by:

/s/ Paul Campanelli

Paul Campanelli
Chairman

/s/ Blaise Coleman

Blaise Coleman
Director

ENDO INTERNATIONAL PLC
NOTES TO COMPANY FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2019 AND 2018

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 Company's directors have considered the potential impact of the COVID-19 global pandemic subsequent event described in Liquidity and Capital resources and concluded that the Company has sufficient liquidity to prepare the financial statements on a going concern basis.

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, 2019. 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 27. 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 17. 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 Financial Statements, 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, 2019 and 2018 were \$759.9 million and \$142.7 million, respectively. No other comprehensive income or losses were applicable for the years ended December 31, 2019 and 2018.

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 profit, 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 profit 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 January 01, 2018 to December 31, 2019 is as follows (in thousands):

	Investment in Subsidiaries
Balance - January 01, 2018, 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	<u>\$ 1,989,676</u>
Capital contribution in respect of share-based payment plans	57,683
Impairment	(693,000)
Balance - December 31, 2019, at cost	<u>\$ 1,354,359</u>

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, 2019 and 2018, 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, 2019 and 2018. As a result of this analysis, the Company determined that the net book value of its Investment in subsidiaries asset exceeded its recoverable amount. The recoverable amount has been determined by reference to the number of outstanding shares multiplied by the closing stock price of Endo International Plc as of December 31 (or the last trading day of the applicable calendar year), adjusted for a control premium which has been determined by analysis of historical pharmaceutical industry deal activity.

As part of the impairment analysis, the Company recorded non-cash impairment charges of \$0.7 billion and \$0.1 billion in the Profit and loss accounts for the years ended December 31, 2019 and 2018, respectively, to reduce the carrying amount of the Company's investment to its recoverable amount. Both the 2019 and 2018 impairments were driven by a combination of factors, including a sustained downturn in Endo's stock price, continued pricing pressures and unfavorable competitive events primarily affecting the Group's Generic Pharmaceuticals and International Pharmaceuticals business segments, among others. If the estimated control premium for the impairment analysis had increased or decreased from management's estimate by 1 percentage point, the impairment of the Investment in subsidiaries balance would have changed by \$10.6 million and \$16.4 million for the years ended December 31, 2019 and 2018, respectively.

NOTE 4. AMOUNTS DUE FROM SUBSIDIARIES

Amounts due from subsidiaries of \$20.6 million and \$52.2 million at December 31, 2019 and 2018, 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. The maturity date of this loan was extended in 2018 to the earlier of ten years from the issuance date or upon written demand by the affiliate. On December 18, 2019, the Company novated its \$24.7 million non-interest bearing note from one affiliate Company to another 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 28 December 2018, the Company novated its \$17.9 million non-interest bearing note from one affiliate Company to another 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 28 December 2018, the Company novated its \$30.1 million non-interest bearing note from one affiliate Company to another 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 the expiration of thirty years from the issuance date or upon written demand by the affiliate. On 28 December 2018, the Company novated its \$25.0 million non-interest bearing note from one Affiliate Company to another affiliate.

On December 18, 2019, the Company issued \$17.2 million in aggregate principal amount of a non-interest bearing note to an affiliate. This loan is due upon the earlier of the expiration of twenty five years from the issuance date or upon written demand by the affiliate.

NOTE 6. AMOUNTS DUE TO SUBSIDIARIES

Amounts due to subsidiaries of \$49.9 million and \$26.9 million at December 31, 2019 and 2018, 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, 2019 (in thousands):

	2019
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 (226,802,609 issued and outstanding) (2018 224,382,791 issued and outstanding)	100
Total share capital	<u>\$ 140</u>
Allotted, called-up and fully paid equity:	
BALANCE, JANUARY 01, 2018	\$ 70
Other	(2)
BALANCE, DECEMBER 31, 2018	<u>\$ 68</u>
Other	—
BALANCE, DECEMBER 31, 2019	<u>\$ 68</u>

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, 2019, approximately 5.5 million ordinary shares were reserved for future grants under the 2015 Plan. As of December 31, 2019, 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 14. 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, 2019 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 its Dublin lease at Minerva House 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, 2019 and 2018 were as follows (in thousands):

	2019	2018
Audit of the Company's individual financials	\$ 104	\$ 115
Audit-related fees	—	—
Tax fees	—	—
Total auditors' remuneration	<u>\$ 104</u>	<u>\$ 115</u>

See Note 28. 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. SUBSEQUENT EVENTS

Subsequent events have been evaluated through May 07, 2020 the date this report is approved by the Audit Committee of the Board of Directors and the Board of Directors.

COVID-19

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China. In March 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. Many countries and localities have announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, suspending all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing shelter-in-place orders (subject to limited exceptions). We are closely monitoring the impact of COVID-19 on all aspects of our business, the pharmaceutical industry and the economy as a whole, including how it has and will continue to impact our workforce, our customers and the patients they serve, our manufacturing and supply chain operations, our R&D programs and regulatory approval processes and our liquidity and access to capital. In addition, we have implemented plans intended to limit the impact of COVID-19 on our business so that we can continue to produce the critical care medicines that hospitals and healthcare providers need to treat patients, including those with COVID-19. The extent to which COVID-19 will impact our business, financial position and operating results cannot be predicted with certainty due to numerous uncertainties related to COVID-19, but any such impact could be material. The Company's directors have considered the potential impact of the COVID-19 global pandemic subsequent event described in Liquidity and Capital resources and concluded that the Company has sufficient liquidity to prepare the financial statements on a going concern basis.

NOTE 12. APPROVAL OF THE FINANCIAL STATEMENTS

The financial statements were approved and authorized for issue by the directors on May 07, 2020.