UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE TRANSITION PERIOD FROM TO
Commission File Number: 001-36326

ENDO INTERNATIONAL PLC

(Exact name of registrant as specified in its charter)

Ireland	**68-0683755**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland	**Not Applicable**
(Address of principal executive offices)	(Zip code)

011-353-1-268-2000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Ordinary shares, nominal value $0.0001 per share	**The NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer	☑	Accelerated filer	☐		
Non-accelerated filer	☐	Smaller reporting company	☐	Emerging growth company	☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the voting common equity (ordinary shares) held by non-affiliates as of June 29, 2018 (the last business day of the registrant's most recently completed second fiscal quarter) was $1,788,232,570 based on a closing sale price of $9.43 per share as reported on the NASDAQ Global Select Market on that date. Ordinary shares held by each officer and director and each beneficial owner of 10% or more (as calculated on June 29, 2018) of the outstanding ordinary shares of the registrant have been excluded since such persons and beneficial owners may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The registrant has no non-voting ordinary shares authorized or outstanding.

Indicate the number of shares outstanding of each of the issuer's classes of ordinary shares, as of the latest practicable date.

Ordinary shares, $0.0001 par value — Number of ordinary shares outstanding as of February 21, 2019: 224,404,247

Documents Incorporated by Reference

Portions of the registrant's proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2019 Annual General Meeting, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2018.

ENDO INTERNATIONAL PLC
INDEX TO FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2018

FORWARD-LOOKING STATEMENTS

Statements contained or incorporated by reference in this document contain information that includes or is based on "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). These statements, including estimates of future revenues, future expenses, future net income and future net income per share, contained in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," which is included in this document, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. We have tried, whenever possible, to identify such statements by words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "projected," "forecast," "will," "may" or similar expressions. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in Part I, Item 1A of this report under the caption "Risk Factors," and as otherwise enumerated herein, could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained or incorporated by reference in this document.

We do not undertake any obligation to update our forward-looking statements after the date of this document for any reason, even if new information becomes available or other events occur in the future, except as may be required under applicable securities law. You are advised to consult any further disclosures we make on related subjects in our reports filed with the Securities and Exchange Commission (SEC) and with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval (SEDAR). Also note that, in Part I, Item 1A we provide a cautionary discussion of the risks, uncertainties and possibly inaccurate assumptions relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. We note these factors for investors as permitted by Section 27A of the Securities Act and Section 21E of the Exchange Act. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this to be a complete discussion of all potential risks or uncertainties.

PART I

Item 1. *Business*

Overview

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

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

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

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

Across all of our businesses, we generated total revenues of $2.95 billion, $3.47 billion and $4.01 billion in 2018, 2017 and 2016, respectively.

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

For branded products, we seek to develop, acquire or license products that have inherent scientific, regulatory, legal and technical complexities and market such products under recognizable brand names that are trademarked. For United States (U.S.) products we develop, after the completion of required clinical trials and testing, we seek approvals from regulatory bodies such as through the submission of New Drug Applications (NDAs) or Biologics License Applications (BLAs) to the U.S. Food and Drug Administration (FDA). In the U.S., upon approval, patents included in the applications are listed in a publication referred to as the Orange Book. We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes, trade secrets, know-how, innovations and all of our intellectual property are important to our business and achieving a competitive position. However, there can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition. Additional information is included throughout this Part I, Item 1.

For generic products, which are the pharmaceutical and therapeutic equivalents of branded products that are generally marketed under their generic (chemical) names rather than their brand names, our focus is on high-barrier-to-entry products, including first-to-file or first-to-market opportunities that are difficult to formulate or manufacture or face complex legal and regulatory challenges. In the U.S., a first-to-file product, also known as a Paragraph IV product, refers to a generic product for which the Abbreviated New Drug Application (ANDA) containing a patent challenge to the corresponding branded product was the first to be filed with the FDA. A first-to-market product refers to a product that is the first marketed generic equivalent of a branded product for reasons apart from statutory marketing exclusivity, such as the generic equivalent of a branded product that is difficult to formulate or manufacture. First-to-file products in the U.S. offer the opportunity for 180 days of generic marketing exclusivity, except for competing authorized generic products, to the extent we are successful in litigating any patent challenges and receive final FDA approval of the products. First-to-market products allow us to mitigate risks from competitive pressure commonly associated with commoditized generic products. Additional information is included throughout this Part I, Item 1.

The four reportable business segments in which we operate are: (1) U.S. Branded - Specialty & Established Pharmaceuticals, (2) U.S. Branded - Sterile Injectables, (3) U.S. Generic Pharmaceuticals and (4) International Pharmaceuticals. Additional information about our reportable business segments is included throughout this Part I, Item 1. The results of operations of our reportable business segments for each of the years ended December 31, 2018, 2017 and 2016 are discussed in Part II, Item 7 of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the heading "RESULTS OF OPERATIONS."

U.S. Branded - Specialty & Established Pharmaceuticals

Our U.S. Branded - Specialty & Established Pharmaceuticals segment, which accounted for approximately 29%, 28% and 29% of total revenues in 2018, 2017 and 2016, respectively, includes a variety of branded prescription products to treat and manage conditions in urology, urologic oncology, endocrinology, pain and orthopedics. The products in this segment include XIAFLEX®, SUPPRELIN® LA, NASCOBAL® Nasal Spray, TESTOPEL®, AVEED®, PERCOCET®, VOLTAREN® Gel, LIDODERM®, FORTESTA® Gel, EDEX® and TESTIM®, among others.

U.S. Branded - Sterile Injectables

Our U.S. Branded - Sterile Injectables segment, which accounted for approximately 32%, 22% and 14% of total revenues in 2018, 2017 and 2016, respectively, consists primarily of branded sterile injectable products such as VASOSTRICT®, ADRENALIN® and APLISOL®, among others, and certain generic sterile injectable products, including ertapenem for injection and ephedrine sulfate injection, among others. These injectable products are manufactured in a sterile facility and are primarily sold through wholesalers, often via an arrangement with a group purchasing organization (GPO), in vial dosages prior to being administered at hospitals, clinics and long-term care facilities.

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

U.S. Generic Pharmaceuticals

Our U.S. Generic Pharmaceuticals segment, which accounted for approximately 34%, 44% and 50% of total revenues in 2018, 2017 and 2016, respectively, consists of a differentiated product portfolio including solid oral extended-release, solid oral immediate-release, liquids, semi-solids, patches, powders, ophthalmics and sprays and includes products in the pain management, urology, central nervous system disorders, immunosuppression, oncology, women's health and cardiovascular disease markets, among others. Our U.S. Generic Pharmaceuticals segment is among the largest U.S. generics companies based on market share. Our largest U.S. Generic Pharmaceuticals manufacturing sites, which handle the production, assembly, quality assurance testing and packaging of our generic products, are located in Chestnut Ridge, New York; Irvine, California and Chennai, India.

International Pharmaceuticals

The International Pharmaceuticals segment, which accounted for approximately 5%, 7% and 7% of total revenues in 2018, 2017 and 2016, respectively, includes a variety of specialty pharmaceutical products sold outside the U.S., primarily in Canada through our operating company Paladin Labs Inc. (Paladin). This segment's key products serve growing therapeutic areas, including attention deficit hyperactivity disorder, pain, women's health and oncology.

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

Our Strategy

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

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

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

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

Our Competitive Strengths

To successfully execute our strategy, we must continue to capitalize on our following core strengths:

Experienced and dedicated management team. We have a highly skilled and customer-focused management team in critical leadership positions across all of Endo. Our senior management team has extensive experience in the pharmaceutical industry and a proven track record of developing businesses and creating value. This experience includes improving business performance through organic revenue growth and through the identification, consummation and integration of licensing and acquisition opportunities.

Focus on the differentiated products of our generics and sterile injectables portfolios. We develop 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. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than products without these characteristics. Our business model continues to focus on being a low cost producer of products in categories with higher barriers to entry and lower levels of competition by leveraging operational efficiency. Our strategy in the U.S. Branded - Sterile Injectables and U.S. Generic Pharmaceuticals segments includes focusing on categories where there are fewer challenges from low-cost operators.

Operational excellence. We have efficient, effective and high-quality manufacturing capabilities across a diversified array of dosage forms. We believe our comprehensive suite of technology, manufacturing and development competencies increases the likelihood of success in commercializing high-barrier-to-entry products and obtaining first-to-file and first-to-market status on future products, yielding more sustainable market share and profitability. For example, our capabilities in the rapidly growing U.S. market for sterile drug products and sterile vial and hormonal capabilities afford us with a broader and more diversified product portfolio and a greater selection of targets for potential development.

We believe that our competitive advantages include our integrated team-based approach to product development that combines our formulation, regulatory, legal, manufacturing and commercial capabilities; our ability to introduce new generic equivalents for brand-name drugs; our quality and cost-effective production; our ability to meet customer and/or patient expectations and the breadth of our existing sterile injectables and generic product portfolio offerings. From time to time, we perform strategic assessments and take steps to optimize our various product portfolios so that we may continue to capitalize on a strong and durable product portfolio and R&D pipeline. We are focused only on those products that deliver acceptable returns on investment, thereby leveraging our existing platform to drive operational efficiency.

Growth of our branded Specialty Products portfolio while leveraging the strength of our Established Products portfolio. We have assembled a portfolio of branded prescription products offered by our U.S. Branded - Specialty & Established Pharmaceuticals segment to treat and manage conditions in urology, urologic oncology, endocrinology, pain and orthopedics. Additional information on these product portfolios is included below under the heading “Products Overview.”

Continuing proactive diversification of our business. Our primary focus is on organic growth. However, we will evaluate and, where appropriate, execute on opportunities to expand through acquisitions of products and companies in areas that will serve patients and customers and that we believe will offer attractive growth characteristics and margins. In particular, we will look to continue to enhance our product lines by acquiring or licensing rights to additional products and regularly evaluating selective acquisition opportunities.

Research and development expertise. Our R&D efforts are focused on the development of a balanced, diversified portfolio of innovative and clinically differentiated product candidates. Through our U.S. Branded - Sterile Injectables and U.S. Generic Pharmaceuticals businesses, we seek out and develop high-barrier-to-entry products, including first-to-file or first-to-market opportunities. We periodically review our generic products pipeline in order to better direct investment toward those opportunities that we expect will deliver the greatest returns. We will continue to evaluate strategic R&D opportunities, with a particular focus on assets with inherently lower risk profiles and clearly defined regulatory pathways. Our current R&D pipeline consists of products in various stages of development. For additional detail, see “Select Development Projects.”

Our R&D and regulatory affairs staff is based primarily in India, Chestnut Ridge, New York; and at our U.S. headquarters in Malvern, Pennsylvania.

Targeted sales and marketing infrastructure. Our sales and marketing activities are primarily based in the U.S. and Canada and focus on the promotion of our Specialty Products portfolio. We market our products directly to specialty physicians, including those specializing in urology, orthopedics, pediatric endocrinology and bariatric surgery. Our sales force also targets retail pharmacies and other healthcare professionals. We distribute our products through independent wholesale distributors, but we also sell directly to retailers, clinics, government agencies, doctors, independent retail and specialty pharmacies and independent specialty distributors. Our marketing policy is designed to provide physicians, pharmacies, hospitals, public and private payers and appropriate healthcare professionals with products and relevant, appropriate medical information. We work to gain access to healthcare authority, pharmacy benefit managers and managed care organizations' formularies (lists of recommended or approved medicines and other products), including Medicare Part D plans and reimbursement lists, by demonstrating the qualities and treatment benefits of our products within their approved indications.

Products Overview

U.S. Branded - Specialty & Established Pharmaceuticals

The following table displays the product revenues to external customers in our U.S. Branded - Specialty & Established Pharmaceuticals segment for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Specialty Products:			
XIAFLEX®	$ 264,638	$ 213,378	$ 189,689
SUPPRELIN® LA	81,707	86,211	78,648
Other Specialty (1)	156,607	153,384	138,483
Total Specialty Products	$ 502,952	$ 452,973	$ 406,820
Established Products:			
PERCOCET®	$ 122,901	$ 125,231	$ 139,211
VOLTAREN® Gel	57,700	68,780	100,642
OPANA® ER	—	83,826	158,938
Other Established (2)	179,279	226,715	360,683
Total Established Products	$ 359,880	$ 504,552	$ 759,474
Total U.S. Branded - Specialty & Established Pharmaceuticals (3)	$ 862,832	$ 957,525	$ 1,166,294

(1) Products included within Other Specialty include NASCOBAL® Nasal Spray, TESTOPEL® and AVEED®.
(2) Products included within Other Established include, but are not limited to, LIDODERM®, FORTESTA® Gel, EDEX® and TESTIM® including the authorized generics of TESTIM® and FORTESTA® Gel.
(3) Individual products presented above represent the top two performing products in each product category and/or any product having revenues in excess of $100 million during any of the years ended December 31, 2018, 2017 and 2016 or $25 million during any quarterly period in 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 category include the following:

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

Established Products Portfolio

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

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

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

Also included within this product portfolio is OPANA® ER, an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. As further discussed in Part II, Item 7 of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations", we voluntarily ceased shipments of OPANA® ER to customers by September 1, 2017.

U.S. Branded - Sterile Injectables

The following table displays the product revenues to external customers in our U.S. Branded - Sterile Injectables segment for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
VASOSTRICT®	$ 453,767	$ 399,909	$ 343,468
ADRENALIN®	143,489	76,523	22,172
Ertapenem for injection	57,668	—	—
Other Sterile Injectables (1)	274,642	274,039	210,759
Total U.S. Branded - Sterile Injectables (2)	$ 929,566	$ 750,471	$ 576,399

(1) Products included within Other Sterile Injectables include, but are not limited to, APLISOL® and ephedrine sulfate injection.
(2) Individual products presented above represent the top two performing products for this segment and/or any product having revenues in excess of $100 million during any of the years ended December 31, 2018, 2017 and 2016 or $25 million during any quarterly period in 2018.

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

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

- Ephedrine sulfate injection, which is an alpha and beta adrenergic agonist and a norepinephrine-releasing agent indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

U.S. Generic Pharmaceuticals

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

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

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

International Pharmaceuticals

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

Select Development Projects

Collagenase Clostridium Histolyticum

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

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

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

Other Pharmaceutical Pipeline

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

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

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

Competition

Branded Pharmaceuticals

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

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

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

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

U.S. Branded - Specialty & Established Pharmaceuticals

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

Several of this segment's products, including, for example, PERCOCET®, VOLTAREN® Gel, LIDODERM® and TESTIM®, face generic competition. In addition, we are aware of certain competitive activities involving certain of our branded products. For a description of material competitive activities, including litigation related to Paragraph IV notices, see Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

U.S. Branded - Sterile Injectables

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

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

Generic Pharmaceuticals

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

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

Newly introduced generic products with limited or no other generic competition typically garner higher prices relative to commoditized generic products. As such, our primary strategy is to compete in the generic product market with a focus on high-value, first-to-file or first-to-market opportunities, regardless of therapeutic category, and products that present significant barriers to entry for reasons such as complex formulation or regulatory or legal challenges. For additional detail, see “Our Competitive Strengths - Focus on the differentiated products of our generics and sterile injectables portfolios.”

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

Major Customers

We primarily sell our generic and branded pharmaceuticals to wholesalers, retail drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, hospitals and government agencies. Our wholesalers and distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies and managed health care organizations. Customers in the managed health care market include health maintenance organizations, nursing homes, hospitals, clinics, pharmacy benefit management companies and mail order customers. Total revenues from direct customers that accounted for 10% or more of our total consolidated revenues during the years ended December 31, 2018, 2017 and 2016 are as follows:

	2018	2017	2016
AmerisourceBergen Corporation	32%	25%	25%
McKesson Corporation	27%	25%	27%
Cardinal Health, Inc.	26%	25%	26%

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

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

Patents, Trademarks, Licenses and Proprietary Property

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

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

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

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

We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes, trade secrets, know-how, innovations and all of our intellectual property are important to our business and achieving a competitive position. Many of our products are sold under trademarks. To achieve a competitive position, we rely on trade secrets, non-patented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable. In addition, as outlined above, we have a number of patent licenses from third parties, some of which may be important to our business. See Note 11. License and Collaboration Agreements in the Consolidated Financial Statements included in Part IV, Item 15 of this report. There can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition.

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

We may find it necessary to initiate litigation to enforce our patent rights, to protect our intellectual property or trade secrets or to determine the scope and validity of the proprietary rights of others. Litigation is costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that we will prevail in any such litigation. See Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Governmental Regulation

United States Food and Drug Administration and Drug Enforcement Administration

The pharmaceutical industry in the U.S. is subject to extensive and rigorous government regulation. The Federal Food, Drug, and Cosmetic Act (FFDCA), the Controlled Substances Act (CSA) and other federal and state statutes and regulations govern or influence the testing, manufacturing, packaging, labeling, storage, record keeping, approval, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in criminal prosecution, fines, civil penalties, recall or seizure of products, total or partial suspension of production and/or distribution, injunctions and refusal of the government to enter into supply contracts or to approve NDAs, ANDAs and/or BLAs.

FDA approval is typically required before any new drug can be marketed. An NDA or BLA is a filing submitted to the FDA to obtain approval of new chemical entities and other innovations for which thorough applied research is required to demonstrate safety and effectiveness in use. The process generally involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an Investigational New Drug application for human clinical testing, which must become effective before human clinical trials may begin in the U.S.;
- approval by an independent institutional review board before each trial may be initiated and continuing review during the trial;
- performance of human clinical trials, including adequate and well-controlled clinical trials in accordance with good clinical practices to establish the safety and efficacy of the proposed drug product for each intended use;
- submission to the FDA of an NDA or BLA for marketing approval, which must include data from preclinical testing and clinical trials;
- satisfactory completion of an FDA pre-approval inspection of the product's manufacturing processes and facility or facilities to assess compliance with the FDA's current Good Manufacturing Practice (cGMP) regulations and/or review of the Chemistry, Manufacturing and Controls section of the NDA or BLA to assess whether the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality, purity and potency;
- satisfactory completion of an FDA advisory committee review, if applicable; and
- approval by the FDA of the NDA or BLA.

Clinical trials are typically conducted in three sequential phases, although the phases may overlap.

- Phase 1 trials generally involve testing the product for safety, adverse effects, dosage, tolerance, absorption, distribution, metabolism, excretion and other elements of clinical pharmacology.
- Phase 2 trials typically involve a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range as well as to gather additional information relating to safety and potential adverse effects.
- Phase 3 trials are undertaken in an expanded patient population, typically at dispersed study sites, in order to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling.

Each trial is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the Investigational New Drug application. Clinical trials are also subject to regulatory inspections by the FDA and other regulatory authorities to confirm compliance with applicable regulatory standards. The process of completing clinical trials for a new drug may take many years and require the expenditures of substantial resources. See Item 1A. Risk Factors - "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."

As a condition of approval of an NDA or BLA, the FDA may require further studies, including Phase 4 post-marketing studies or post-marketing data reporting. Results of post-marketing programs may limit or expand the future marketing of the products.

For some drugs, the FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to confirm that a drug's benefits outweigh its risks. REMS could include medication guides, physician communication plans or other elements. See Item 1A. Risk Factors - "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."

In most instances, FDA approval of an ANDA is required before a generic equivalent of an existing or reference-listed drug can be marketed. The ANDA process is abbreviated in that the FDA waives the requirement of conducting complete preclinical and clinical studies and generally instead relies principally on bioequivalence studies. Bioequivalence generally involves a comparison of the rate of absorption and levels of concentration of a generic drug in the body with those of the previously approved drug. When the rate and extent of absorption of systemically acting test and reference drugs are considered the same under the bioequivalence requirement, the two drugs are considered bioequivalent and are generally regarded as therapeutically equivalent, meaning that a pharmacist can substitute the product for the reference-listed drug. Under certain circumstances, an ANDA may also be submitted for a product authorized by approval of an ANDA suitability petition. Such petitions may be submitted to secure authorization to file an ANDA for a product that differs from a previously approved drug in active ingredient, route of administration, dosage form or strength. In September 2007 and July 2012, Congress re-authorized pediatric testing legislation, which now requires ANDAs approved via the suitability petition route to conduct pediatric testing. The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the manufacturer of the reference-listed drug is entitled to one or more statutory exclusivity periods, during which the FDA is prohibited from approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, thus blocking ANDAs from being approved until after the patent expiration date.

Certain of our products are or could become regulated and marketed as biologic products pursuant to BLAs. Our BLA-licensed products were licensed based on a determination by the FDA of safety, purity and potency as required under the Public Health Service Act (PHSA). Although the ANDA framework referenced above does not apply to generics of BLA-licensed biologics, there is an abbreviated licensure pathway for products deemed to be biosimilar to, or interchangeable with, FDA-licensed reference biological products pursuant to the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The BPCIA framework was enacted as part of the Patient Protection and Affordable Care Act (PPACA) and could be impacted by ongoing litigation regarding the legality of the PPACA. Under the BPCIA, following the expiration of a 12-year reference exclusivity period, the FDA may license, under section 351(k) of the PHSA, a biologic that it determines is biosimilar to, or interchangeable with, a reference product licensed under section 351(a) of the PHSA. Biosimilarity is defined to mean that the section 351(k) product is highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and that there are no clinically meaningful differences between the section 351(k) product and the reference product in terms of the safety, purity and potency. To be considered interchangeable, a product must be biosimilar to the reference product, be expected to produce the same clinical result as the reference product in any given patient and, if administered more than once to an individual, the risks in terms of safety or diminished efficacy of alternating or switching between use of the product and its reference product is not greater than the risk of using the reference product without such alternation or switch.

Once any regulatory exclusivity period for our BLA-licensed biologics expires, the FDA may approve another company's BLA for a biosimilar or interchangeable version of our product. Although licensure of a biosimilar or interchangeable product is generally expected to require less than the full complement of product-specific preclinical and clinical data required for innovator products, the FDA has considerable discretion over the kind and amount of scientific evidence required to demonstrate biosimilarity and interchangeability.

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

The 21st Century Cures Act (Cures Act) was signed into law on December 13, 2016. The Cures Act includes various provisions to accelerate the development and delivery of new treatments, such as those intended to expand the types of evidence manufacturers may submit to support FDA drug approval, to encourage patient-centered drug development, to liberalize the communication of healthcare economic information to payers and to create greater transparency with regard to manufacturer expanded access programs. Central to the Cures Act are provisions that enhance and accelerate the FDA's processes for reviewing and approving new drugs and supplements to approved NDAs. These include, but are not limited to, provisions that (i) require the FDA to establish a program to evaluate the potential use of real-world evidence to help to support the approval of a new indication for an approved drug and to help to support or satisfy post-approval study requirements, (ii) provide that the FDA may rely upon qualified data summaries to support the approval of a supplemental application with respect to a qualified indication for an already approved drug, (iii) require the FDA to issue guidance for purposes of assisting sponsors in incorporating complex adaptive and other novel trial designs into proposed clinical protocols and applications for new drugs and (iv) require the FDA to establish a process for the qualification of drug development tools for use in supporting or obtaining FDA approval for or investigational use of a drug. The FDA has taken steps to implement the Cures Act, including issuing various guidance documents.

The Cures Act also included $1 billion in new funding to address what the act refers to as the "opioid abuse crisis." Specifically, the Cures Act authorizes the awarding of grants to states for the purpose of addressing opioid abuse within each state, with preference to be given to states with an incidence or prevalence of opioid use disorders that is substantially higher relative to other states. Funding shall be used by states to supplement opioid abuse prevention and treatment activities, such as improving prescription drug monitoring programs, implementing prevention activities, providing training for health care providers and expanding access to opioid treatment programs. States receiving such grants shall be required to report on activities funded by the grant in the substance abuse block grant report.

We cannot determine what effect changes in the FDA's laws or regulations (including legal or regulator interpretations), when and if promulgated, or advisory committee meetings may have on our business in the future. Changes could, among other things, require expanded or different labeling, additional testing, the recall or discontinuance of certain products and additional recordkeeping. See Item 1A. Risk Factors - "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."

A sponsor of an NDA is required to identify, in its application, any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files an ANDA or NDA under Section 505(b)(2) of the FFDCA must make a certification in respect to any listed patents for the reference drug. The FDA may not approve such an ANDA or 505(b)(2) application until expiration of the reference drug's listed patents unless (i) the generic applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder of the NDA for the listed drug of the basis upon which the patents are challenged and (ii) the holder of the listed drug does not sue the later applicant for patent infringement within 45 days of receipt of notice. Under the current law, if an infringement suit is filed, the FDA may not approve the later application until the earliest of: (i) 30 months after submission, (ii) entry of an appellate court judgment holding the patent invalid, unenforceable or not infringed, (iii) such time as a court may order or (iv) expiration of the patent.

One of the key motivators for challenging patents is the 180-day marketing exclusivity period granted to the developer of a generic version of a product that is the first to have its ANDA accepted for filing by the FDA and whose filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (a Paragraph IV certification) and that otherwise does not forfeit eligibility for the exclusivity. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (2003 Medicare Act), with accompanying amendments to the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act), this marketing exclusivity would begin to run upon the earlier of the commercial launch of the generic product or upon an appellate court decision in the generic company's favor or in favor of another ANDA applicant who had filed with a Paragraph IV certification and has tentative approval. In addition, the holder of the NDA for the listed drug may be entitled to certain non-patent exclusivity during which, depending on the type of exclusivity, the FDA either cannot accept or approve an application for a competing ANDA generic product or 505(b)(2) NDA product with the same active moiety for a protected condition of use.

The FDA also regulates pharmacies and outsourcing facilities that prepare "compounded" drugs pursuant to section 503A and 503B of the FFDCA, respectively. For instance, pharmacies may compound drugs for an identified individual based on the receipt of a valid prescription order, or notation approved by the prescribing practitioner, that a compounded product is necessary for the identified patient. Similarly, outsourcing facilities may compound drugs and sell them to healthcare providers, but not wholesalers or distributors. Although section 503A pharmacies and section 503B outsourcing facilities are subject to many regulatory requirements, compounded drugs are not subject to premarket review by the FDA and, therefore, may not have the same level of safety and efficacy assurances of drugs subject to premarket review and approval by the FDA. Because they are not subject to premarket review, compounded drugs are frequently lower cost than either branded or generic drug products.

The FDA enforces regulations to require that the methods used in, and the facilities and controls used for, the manufacture, processing, packing and holding of drugs conform to cGMPs. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of manufacturing operations. Compliance with the regulations requires a continuous commitment of time, money and effort in all operational areas.

The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packing, testing and holding of the drugs subject to NDAs and ANDAs. In addition, manufacturers of both pharmaceutical products and active pharmaceutical ingredients (APIs) used to formulate drugs also ordinarily undergo pre-approval inspections. Failure of any facility to pass a pre-approval inspection will result in delayed approval.

The FDA also conducts periodic inspections of drug facilities to assess the cGMP status of marketed products. Following such inspections, the FDA may issue an untitled letter as an initial correspondence that cites violations that do not meet the threshold of regulatory significance for a Warning Letter. FDA guidelines also provide for the issuance of Warning Letters for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. Finally, the FDA could issue a Form 483 Notice of Inspectional Observations, which could require modification to certain activities identified during the inspection. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions.

Imported API and other components needed to manufacture our products could be rejected by U.S. Customs. In respect to domestic establishments, the FDA could initiate product seizures or request, or in some instances require, product recalls and seek to enjoin or otherwise limit a product's manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products and classifying that company as an unacceptable supplier, thereby disqualifying that company from selling products to federal agencies.

Certain of our subsidiaries sell products that are "controlled substances" as defined in the CSA and implementing regulations, which establish certain security and recordkeeping requirements administered by the Drug Enforcement Administration (DEA). The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our products are listed by the DEA as Schedule II or III substances under the CSA. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation.

The DEA limits the availability of the active ingredients that are subject to the CSA used in several of our products as well as 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 and produce these substances. As a result, our quotas may not be sufficient to meet commercial demand or complete clinical trials. Moreover, the DEA may adjust these quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. See Item 1A. Risk Factors - "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."

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Annual registration is required for any facility that manufactures, tests, distributes, dispenses, imports or exports any controlled substance. The facilities must have the security, control, accounting mechanisms and monitoring systems required by the DEA to prevent loss and diversion of controlled substances and to comply with reporting obligations. Failure to maintain compliance can result in enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke or restrict those registrations or, with the U.S. Department of Justice, seek to impose civil penalties. In certain circumstances, violations could result in criminal proceedings.

Individual states also regulate controlled substances and we, as well as our third-party API suppliers and manufacturers, are subject to such regulation by several states with respect to the manufacture and distribution of these products.

Government Benefit Programs

As described further in Item 1A. Risk Factors, statutory and regulatory requirements for government healthcare programs such as Medicaid, Medicare and TRICARE govern access and provider reimbursement levels, and provide for other cost-containment measures such as requiring pharmaceutical companies to pay rebates or refunds for certain sales of products reimbursed by such programs, or subjecting products to certain price ceilings. In addition to the cost-containment measures described in Item 1A. Risk Factors, drug sales to retail pharmacies under the TRICARE Retail Pharmacy Program are subject to certain price ceilings which require manufacturers to, among other things, pay refunds for prescriptions filled based on the applicable ceiling price limits. Beginning in the first quarter of 2017, pursuant to the Bipartisan Budget Act of 2015, drug manufacturers are required to pay additional rebates to state Medicaid programs if the prices of their non-innovator drugs rise at a rate faster than inflation (as continues to be the case for innovator products).

The federal government may continue to pursue legislation aimed at containing or reducing payment levels for prescription pharmaceuticals paid for in whole or in part with government funds. State governments also may continue to enact similar cost containment or transparency legislation. These efforts could have material consequences for the pharmaceutical industry and the Company.

From time to time, legislative changes are made to government healthcare programs that impact our business. Congress continues to examine various Medicare and Medicaid policy proposals that may result in a downward pressure on the prices of prescription drugs in these programs. See Item 1A. Risk Factors - "The availability of third party reimbursement for our products is uncertain, and thus we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third party reimbursement is not adequately provided."

Under the PPACA, pharmaceutical manufacturers of branded prescription drugs must pay an annual fee to the federal government. Each individual pharmaceutical manufacturer must pay a prorated share of the total industry fee (the fee was $3 billion for 2016, $4 billion for 2017 and $4.1 billion for 2018 and will be $2.8 billion in 2019 and for years thereafter) based on the dollar value of its branded prescription drug sales to specified federal programs. PPACA also expanded health insurance coverage to many previously uninsured Americans, through a combination of federal subsidies for lower-income individuals who enrolled in health plans through health insurance exchanges and enabling states to expand Medicaid eligibility with the federal government paying a high share of the cost.

Uncertainty continues to exist about the future of federal subsidies and of insurance coverage expansion as the current administration and congressional leaders continue to express interest in repealing these PPACA provisions and replacing them with alternatives that may be less costly and provide state Medicaid programs and private health plans more flexibility. The Tax Cuts and Jobs Act of 2017 (TCJA) repealed the requirement that individuals maintain health insurance coverage or face a penalty (known as the individual mandate). The removal of this provision, coupled with the threat of the repeal of other PPACA provisions, as well as the outcome of court challenges to the PPACA (including a December 2018 ruling in the U.S. District Court for the Northern District of Texas finding the PPACA to be unconstitutional, which is pending appeal), threaten the stability of the insurance marketplace and may have consequences for the coverage and accessibility of prescription drugs.

Healthcare Fraud and Abuse Laws

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, violations of which can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws are potentially applicable to us as both a manufacturer and a supplier of products reimbursed by federal healthcare programs, and they also apply to hospitals, physicians and other potential purchasers of our products.

The federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b) prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Remuneration is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, coupons, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Under the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b, a person or entity need not have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim, including items or services resulting from a violation of 42 U.S.C. § 1320a-7b, constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The federal Anti-Kickback Statute and implementing regulations provide for certain exceptions for "safe harbors" for certain discounting, rebating or personal services arrangements, among other things. However, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult. Violations of the federal Anti-Kickback Statute can result in significant criminal fines, exclusion from participation in Medicare and Medicaid and follow-on civil litigation, among other things, for both entities and individuals.

Other federal healthcare fraud-related laws also provide criminal liability for violations. The Criminal Healthcare Fraud statute, 18 U.S.C. § 1347, prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. Federal criminal law at 18 U.S.C. § 1001, among other sections, prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. See Item 1A. Risk Factors - "We are subject to various regulations pertaining to the marketing of our products and services."

The civil False Claims Act and similar state laws impose liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* provisions of the False Claims Act and similar state laws allow a private individual to bring civil actions on behalf of the federal or state government and to share in any monetary recovery. The Federal Physician Payments Sunshine Act and similar state laws impose reporting requirements for various types of payments to physicians and teaching hospitals. Failure to comply with reporting requirements under these laws could subject manufacturers and others to substantial civil money penalties. In addition, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical and medical device companies for alleged false or misleading statements in connection with the marketing, promotion and/or sale of pharmaceutical and medical device products, including state investigations of the Company regarding the Company's vaginal mesh devices and investigations and litigation by certain government entities regarding the Company's marketing of opioid products.

International Regulations

Through our international operations, the Company is subject to laws and regulations that differ from those under which the Company operates in the U.S. In most cases, non-U.S. regulatory agencies evaluate and monitor the safety, efficacy and quality of pharmaceutical products, govern the approval of clinical trials and product registrations and regulate pricing and reimbursement. Certain international markets have differing product preferences and requirements and operate in an environment of government-mandated, cost-containment programs, including price controls, such as the Patented Medicine Prices Review Board in Canada. Certain governments have placed restrictions on physician prescription levels and patient reimbursements, emphasized greater use of generic drugs and enacted across-the-board price cuts as methods of cost control.

Whether or not FDA approval has been obtained for a product, approval of the product by comparable regulatory authorities of other governments must be obtained prior to marketing the product in those jurisdictions. The approval process may be more or less rigorous than the U.S. process and the time required for approval may be longer or shorter than is required in the U.S.

Service Agreements

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

For a description of our significant manufacturing, supply and other service agreements, see Note 11. License and Collaboration Agreements and Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

We primarily purchase our raw materials for the production and development of our products in the open market from third party suppliers. However, some raw materials are only available from one source. We attempt, when possible, to mitigate our raw material supply risks through inventory management and alternative sourcing strategies. We are required to identify the suppliers of all raw materials for our products in the drug applications that we file with the FDA. If the raw materials from an approved supplier for a particular product become unavailable, we would be required to qualify a substitute supplier with the FDA, which would likely interrupt manufacturing of the affected product. See Item 1A. Risk Factors for further discussion on the risks associated with the sourcing of our raw materials.

License & 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 Company enters into strategic alliances and collaborative arrangements with third parties, which give the Company rights to develop, manufacture, market and/or sell pharmaceutical products, the rights to which are primarily owned by these third parties. These alliances and arrangements can take many forms, including licensing arrangements, co-development and co-marketing agreements, co-promotion arrangements, research collaborations and joint ventures. Such alliances and arrangements enable us to share the risk of incurring all research and development expenses that do not lead to revenue-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 Company not opted for a development partner. For a discussion of material agreements and acquisitions, including agreement terms and status, see our disclosures in Note 5. Acquisitions and Note 11. License and Collaboration Agreements in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Environmental Matters

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

Employees

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

Executive Officers of the Registrant

The following table sets forth information as of February 28, 2019 regarding each of our current executive officers:

Name	Age	Position and Offices
Paul V. Campanelli	56	President and Chief Executive Officer and Director
Blaise Coleman	45	Executive Vice President, Chief Financial Officer
Terrance J. Coughlin	53	Executive Vice President, Chief Operating Officer
Tony Pera	61	President, Par Pharmaceutical
Matthew J. Maletta	47	Executive Vice President, Chief Legal Officer
Patrick Barry	51	Executive Vice President and Chief Commercial Officer

Biographies

Our executive officers are briefly described below:

PAUL V. CAMPANELLI, was appointed President, Chief Executive Officer and a Director effective September 23, 2016. Mr. Campanelli joined Endo in 2015 as the President of Par Pharmaceutical, leading Endo's fully integrated U.S. Generics business, following Endo's acquisition of Par Pharmaceutical. Prior to joining Endo, he had served as Chief Executive Officer of Par Pharmaceutical Companies, Inc. following the company's September 2012 acquisition by TPG. Prior to the TPG acquisition, Mr. Campanelli served as Chief Operating Officer and President of Par Pharmaceutical, Inc. from 2011 to 2012. At Par Pharmaceutical Inc., Mr. Campanelli had also served as Senior Vice President, Business Development & Licensing; Executive Vice President and President of Par Pharmaceutical, Inc.; and was named a Corporate Officer by its board of directors. He also served on the board of directors of Sky Growth Holdings Corporation from 2012 until 2015. Mr. Campanelli joined Par Pharmaceutical Companies, Inc. in 2001. Prior to joining Par Pharmaceutical Companies, Inc., Mr. Campanelli served as Vice President, Business Development at Dr. Reddy's Laboratories Ltd. where he was employed from 1992 to 2001. Mr. Campanelli earned his Bachelor of Science degree from Springfield College.

BLAISE COLEMAN, was appointed Executive Vice President and Chief Financial Officer effective December 19, 2016. Mr. Coleman was serving as Endo's Interim Chief Financial Officer since November 22, 2016. He joined Endo in January 2015 as Vice President of Corporate Financial Planning & Analysis, and was then promoted to Senior Vice President, Global Finance Operations in November 2015. Prior to joining Endo, Mr. Coleman held a number of finance leadership roles with AstraZeneca, a global biopharmaceutical company, most recently as the Chief Financial Officer of the AstraZeneca/Bristol-Myers Squibb US Diabetes Alliance from January 2013 until January 2015. Prior to that, he was the Head of Finance for the AstraZeneca Global Medicines Development organization based in Mölndal, Sweden from September 2011 to January 2013. Mr. Coleman joined AstraZeneca as Senior Director Commercial Finance for the US Cardiovascular Business in November 2007. He joined AstraZeneca from Centocor, a wholly owned subsidiary of Johnson & Johnson, where he held positions in both the Licenses & Acquisitions and Commercial Finance organizations. Mr. Coleman's move to Centocor in early 2003 followed 7 years' experience with the global public accounting firm, PricewaterhouseCoopers LLP. Mr. Coleman is a Certified Public Accountant; he holds a Bachelor of Science degree in accounting from Widener University and an M.B.A. from the Fuqua School of Business at Duke University.

TERRANCE J. COUGHLIN, was appointed Executive Vice President and Chief Operating Officer effective November 1, 2016. In this role, Mr. Coughlin has responsibility for Manufacturing and Technical Operations and R&D across the enterprise. Most recently, Mr. Coughlin served as Vice President, Operations of Par Pharmaceutical Companies, Inc., a subsidiary of Endo. Prior to Endo's acquisition of Par in September 2015, Mr. Coughlin was the Chief Operating Officer of Par Pharmaceutical Companies, Inc. Prior to joining Par, Mr. Coughlin held a number of leadership roles with Glenmark Generics, Inc. USA/Glenmark Generics Limited latterly as the President and Chief Executive Officer of Glenmark Generics, Inc. USA/Glenmark Generics Limited. Prior to this, Mr. Coughlin had the overall responsibility for Glenmark's North American, Western European and Eastern European generics businesses, as well as its global active pharmaceutical ingredient business and generics operations in India. Prior to joining Glenmark, Mr. Coughlin served as Senior Vice President at Dr. Reddy's Laboratories, Inc. Mr. Coughlin began his career in 1988 with Wyckoff Chemical Company, Inc. Mr. Coughlin earned a B.S. in chemistry from Central Michigan University.

TONY PERA, was named President, Par Pharmaceutical effective November 1, 2016. In this role, Mr. Pera leads Endo's U.S. Generics business including responsibility and oversight of Par Generic and Par Sterile sales teams, as well as Par's marketing & business analytics group. Most recently, Mr. Pera served as Chief Commercial Officer of Par Pharmaceutical. He joined Par in February 2014 as part of Par's acquisition of JHP Pharmaceutical, where he held a similar position. As Chief Commercial Officer, Mr. Pera was responsible for all sales, marketing, pricing and customer operations functions for Par. Prior to JHP and Par, Mr. Pera was Senior Vice President of Supply Chain Management for AmerisourceBergen (ABC), a major U.S. pharmaceutical wholesaler, for approximately five years. Prior to ABC, he held numerous senior leadership positions with generic drug companies including APP (now Fresenius Kabi), Bedford Laboratories and LyphoMed. Mr. Pera started his career as a sales representative for the parenteral products division of Baxter. Mr. Pera holds a B.S. in Business Administration from the University of Illinois in Champaign and an M.B.A. from DePaul University.

MATTHEW J. MALETTA, was appointed Executive Vice President, Chief Legal Officer effective May 4, 2015. Prior to joining Endo, Mr. Maletta served as Vice President, Associate General Counsel and Corporate Secretary of Allergan, Inc. In this position, he served as an advisor to the CEO and Board of Directors and supervised several large M&A transactions and takeover defense activities, including Allergan's acquisition of Inamed and Actavis' acquisition of Allergan. Mr. Maletta first joined Allergan in 2002 as Corporate Counsel and Assistant Secretary and during his tenure, held various roles of increased responsibility. Prior to joining Allergan, Mr. Maletta was in private practice, focusing on general corporate matters, finance, governance, securities and transactions. He holds a B.A. degree in political science from the University of Minnesota, summa cum laude, and a J.D. degree, cum laude, from the University of Minnesota Law School.

PATRICK BARRY, was appointed Executive Vice President and Chief Commercial Officer effective February 26, 2018. In this role, he has responsibility for all commercial activities for U.S. Branded Pharmaceuticals, including strategy, new product planning, marketing, sales as well as managed care and patient access responsibilities. Mr. Barry joined Endo in December 2016 as Senior Vice President, U.S. Branded Pharmaceuticals. Prior to joining Endo, Mr. Barry worked at Sanofi S.A. from April 1992 until December 2016, holding roles of increasing responsibility in areas such as Sales Leadership, Commercial Operations, Marketing, Launch Planning and Training and Leadership Development. Most recently, he served at Sanofi S.A. as its General Manager and Head of North America General Medicines starting in September 2015 and as Vice President and Head of U.S. Specialty from April 2014 until August 2015. During this time, Mr. Barry oversaw three complex and diverse businesses with responsibility for leading sales and marketing activities for branded and generic products across the U.S. and Canada. He has a diverse therapeutic experience including aesthetics and dermatology, oncology, urology, orthopedics and medical device and surgical experience. He has an M.B.A. from Cornell University, Johnson School of Management and a B.A. in Public Relations and Marketing from McKendree University.

We have employment agreements with each of our executive officers.

Available Information

Our internet address is www.endo.com. The contents of our website are not part of this Annual Report on Form 10-K, and our internet address is included in this document as an inactive textual reference only. We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the Securities and Exchange Commission.

You can access our filings through the SEC's internet site: www.sec.gov *(intended to be an inactive textual reference only).*

You may also access copies of the Company's filings with the Canadian Securities Administrators on SEDAR through their internet site: www.sedar.com *(intended to be an inactive textual reference only).*

Item 1A. ***Risk Factors***

We operate in a highly competitive industry.

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

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

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

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

If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of our branded drugs, our sales may suffer.

Under the Hatch-Waxman Act, the FDA can approve an ANDA for a generic bioequivalent version of a previously approved drug without requiring the ANDA applicant to undertake the full clinical testing necessary to obtain approval to market a new branded drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its generic product is the same as the referenced listed drug with respect to the active ingredient and is bioequivalent to the branded product.

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

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

In the case of VASOSTRICT®, Par Sterile Products, LLC (PSP) and Par Pharmaceutical, Inc. (PPI) received a notice letter from Eagle Pharmaceuticals, Inc. (Eagle) in April 2018 advising of the filing by such company of an ANDA for a generic version of VASOSTRICT® (vasopressin IV solution (infusion)). The Paragraph IV notice refers to patents the Company has listed in the Orange Book covering either vasopressin-containing pharmaceutical compositions or methods of using a vasopressin-containing dosage form to increase blood pressure in humans. In May 2018, PPI, PSP and Endo Par Innovation Company, LLC (EPIC) filed a lawsuit against Eagle in the United States District Court for the District of Delaware within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. We intend to vigorously defend VASOSTRICT®'s intellectual property rights and to pursue all available legal, business and regulatory avenues in defense of VASOSTRICT®, including enforcement of the product's intellectual property rights. However, there can be no assurance that our defense will be successful. If a generic version of VASOSTRICT® were introduced to the market before 2020, our revenues from VASOSTRICT® would decrease significantly and, depending on the timing of such introduction and its effect on VASOSTRICT® pricing, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

There are currently ongoing legal proceedings brought by us and/or our subsidiaries, and in certain cases our third party partners, against manufacturers seeking FDA approval for generic versions of our products. For a description of the material related legal proceedings, see Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

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

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

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

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

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

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

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

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

For example, we and our subsidiaries, along with other manufacturers of prescription opioid medications, are the subject of lawsuits and have received subpoenas and other requests for information from various state and local government agencies regarding the sale, marketing and/or distribution of prescription opioid medications. Numerous claims against opioid manufacturers have been and may continue to be filed by or on behalf of states, counties, cities, Native American tribes, other government-related persons or entities, hospitals, health systems, unions, health and welfare funds, other third-party payers and/or individuals. See Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for more information. In these cases, plaintiffs seek various remedies, including without limitation, declaratory and/or injunctive relief; compensatory, punitive and/or treble damages; restitution, disgorgement, civil penalties, abatement, attorneys' fees, costs and/or other relief. In addition to direct expenditures for damages, settlement and defense costs in connection with these claims, proceedings and investigations, there is a possibility of loss of revenues, injunctions and disruption of business. Furthermore, we and other manufacturers of prescription opioid medications have been, and will likely continue to be, subject to negative publicity and press, which could harm our brand and the demand for our products. There are also regulatory and legislative proposals being made that could impact us and other manufacturers of prescription opioid medications. See the risk factor "Our business and financial condition may be adversely affected by legislation" for more information.

Our current and former products may cause, or may appear to cause, serious adverse side effects or potentially dangerous drug interactions if misused or improperly prescribed or as a result of faulty surgical technique. For example, we and/or certain of our subsidiaries and certain other manufacturers have been named as defendants in multiple lawsuits in various federal and state courts alleging personal injury resulting from use of transvaginal surgical mesh products designed to treat pelvic organ prolapse and stress urinary incontinence. 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 pelvic organ prolapse. Although we have not sold transvaginal surgical mesh products since March 2016, it is possible that the outcome of the advisory committee meeting and the FDA's actions, if any, based on the outcome of the advisory committee meeting could result in additional litigation against the Company. See Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for more information.

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

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

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

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

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

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

See Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion of the forgoing and other material legal proceedings.

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

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

- causing a substantial portion of our cash flows from operations to be dedicated to the payment of legal or related expenses and therefore unavailable for other purposes, including the payment of principal and interest on our indebtedness, our operations, capital expenditures and future business opportunities;
- limiting our ability to incur additional borrowings under our existing facilities or to obtain additional debt or equity financing for working capital, capital expenditures, business development, debt service requirements, acquisitions or general corporate or other purposes, or to refinance our indebtedness;
- limiting our ability to adjust to changing market conditions, causing us to be more vulnerable to periods of negative or slow growth in the general economy or in our business, causing us to be unable to carry out capital spending that is important to our growth and placing us at a competitive disadvantage;
- limiting our ability to attract and retain key personnel;

- causing us to be unable to maintain compliance with or making it more difficult for us to satisfy our financial obligations under certain of our outstanding debt obligations, causing a downgrade of our debt and long-term corporate ratings and exposing us to potential events of default (if not cured or waived) under financial and operating covenants contained in our or our subsidiaries' outstanding indebtedness that could have a material adverse effect on our business, financial condition, results of operations, liquidity and cash flows.

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

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

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

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

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

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

The Company also relies on trade secrets and other unpatented proprietary information, which it generally seeks to protect by confidentiality and nondisclosure agreements with its employees, consultants, advisors and partners. These agreements may not effectively prevent disclosure of confidential information and may not provide the Company with an adequate remedy in the event of unauthorized disclosure. For example, in August 2017, we filed a complaint against QuVa Pharma, Inc. and certain individual defendants in the U.S. District Court for the District of New Jersey alleging misappropriation in violation of the federal Defend Trade Secrets Act, New Jersey's Trade Secrets Act and New Jersey common law, as well as unfair competition, breach of contract, breach of fiduciary duty, breach of the duty of loyalty, tortious interference with contractual relations and breach of the duty of confidence in connection with VASOSTRICT®, a vasopressin-based cardiopulmonary drug. For more information regarding this litigation, see Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report. Even if third parties misappropriate or infringe upon our proprietary rights, we may not be able to discover or determine the extent of any such unauthorized use and we may not be able to prevent third parties from misappropriating or infringing upon our proprietary rights. In addition, if the Company's employees, scientific consultants or partners develop inventions or processes that may be applicable to the Company's existing products or products under development, such inventions and processes will not necessarily become the Company's property and may remain the property of those persons or their employers.

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

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

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

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

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

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

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

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

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

For the years ended December 31, 2018, 2017 and 2016, we recorded asset impairment charges of $0.9 billion, $1.2 billion and $3.8 billion, respectively, which related primarily to goodwill and other intangible assets. Refer to Note 10. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report for examples and a discussion of material impairment tests and impairment charges during the years ended years ended December 31, 2018, 2017 and 2016. The procedures and assumptions used in our goodwill and intangible assets impairment testing are discussed in Part II, Item 7 of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the caption "CRITICAL ACCOUNTING ESTIMATES" and in Note 10. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, we are subject to the Federal Drug Supply Chain Security Act (DSCSA) enacted by the U.S. government, which requires development of an electronic pedigree to track and trace each prescription drug at the salable unit level through the distribution system, which will be effective incrementally over a 10-year period. Compliance with DSCSA and future U.S. federal or state electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens.

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

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

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

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

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

- diversion of management's attention to integration matters;
- difficulties in achieving anticipated cost or tax savings, synergies, business opportunities and growth prospects from the combination of the businesses;
- difficulties in the integration of operations and systems;
- the impact of pre-existing legal and/or regulatory issues;

- difficulties in conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the companies;
- difficulties in the assimilation of employees and retention of key personnel;
- difficulties in managing the expanded operations of a significantly larger and more complex company;
- challenges in retaining existing customers and obtaining new customers;
- potential unknown liabilities or larger liabilities than projected, adverse consequences and unforeseen increased expenses associated with the merger; and
- difficulties in coordinating a geographically dispersed organization.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Manufacturers of prescription opioid medications have been the subject of significant civil and criminal investigatory and enforcement action even in cases where such medications have received approval from the FDA or similar regulatory authorities. In addition, numerous governmental and private persons and entities are pursuing civil litigation against opioid manufacturers and distributors, invoking current laws and regulations relating to opioids and/or other prescription medicines, as well as novel uses of other laws that seek to hold accountable opioid manufacturers for opioid misuse. See Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for more information.

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

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

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

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

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

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

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

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

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

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

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

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

Total revenues from direct customers who accounted for 10% or more of our total consolidated revenues during the years ended December 31, 2018, 2017 and 2016 are as follows:

	2018	2017	2016
AmerisourceBergen Corporation	32%	25%	25%
McKesson Corporation	27%	25%	27%
Cardinal Health, Inc.	26%	25%	26%

Revenues from these customers are included within each of our segments. Accordingly, our revenues, 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 inventory objectives or other factors. In addition, if we were to lose the business of any of these customers, or if any were to experience difficulty in paying us on a timely basis, our total revenues, profitability and cash flows could be materially adversely affected.

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

Third party manufacturers currently manufacture a significant amount of our products pursuant to contractual arrangements. Certain of our manufacturers currently constitute the sole source of our products. For example, Teikoku Seiyaku Co., Ltd. is our sole source of LIDODERM® and Sandoz Inc. 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, which could be the result of one or many factors outside of our control, could delay or prevent our ability to achieve sales expectations, cause interruptions in our supply of products to customers, cause us to incur failure-to-supply penalties, disrupt our operations or cause reputational harm to our company, any or all of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- FDA approval or disapproval of any of the drug applications we have submitted;
- the success or failure of our clinical trials;
- new data or new analyses of older data that raises potential safety or effectiveness issues concerning our approved products;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the imposition of additional U.S. and non-U.S. governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. and/or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;
- economic and political instability or disruptions, including local and regional instability, or disruptions due to natural disasters, such as severe weather and geological events, disruptions due to civil unrest and hostilities, rioting, military activity, terror attacks or armed hostilities;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions including foreign exchange controls;
- supply disruptions and increases in energy and transportation costs;

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

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

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

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

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

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

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

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

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

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

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

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

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

A breach of any of these covenants could result in a default under our indebtedness. If there were an event of default under any of the agreements relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately, terminate all commitments to extend further credit, foreclose against all the assets comprising the collateral securing or otherwise supporting the debt and pursue other legal remedies. The instruments governing our debt contain cross-default or cross-acceleration provisions that may cause all of the debt issued under such instruments to become immediately due and payable as a result of a default under an unrelated debt instrument. An event of default or an acceleration under one debt agreement could cause a cross-default or cross-acceleration of other debt agreements. Our assets and cash flows may be insufficient to fully repay borrowings under our outstanding debt instruments if the obligations thereunder were accelerated upon an event of default. We may need to conduct asset sales or elect to pursue other alternatives, including proceedings under applicable insolvency laws relating to some or all of our business. Any or all of the above could have a material adverse effect on our business, financing activities, financial condition and operations. For a description of our indebtedness, see Note 14. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

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

- changes to U.S. federal tax rates;
- expanded limitations on the deductibility of interest;
- immediate expensing of capital expenditures;
- the migration from a "worldwide" system of taxation to a "territorial" system;

- the creation of an anti-base erosion minimum tax system; and
- the modification or repeal of many business deductions and credits.

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

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

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

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

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

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

The IRS may not agree with the conclusion that we should be treated as a non-U.S. corporation for U.S. federal income tax purposes.

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal income tax purposes pursuant to Section 7874 of the Code. A corporation is generally considered a tax resident in the jurisdiction of its organization or incorporation for U.S. federal income tax purposes. Because we are an Irish incorporated entity, we would generally be classified as a non-U.S. corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 provides an exception pursuant to which a non-U.S. incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal income tax purposes.

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

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

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

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

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

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

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

Our ability to use U.S. tax attributes to offset U.S. taxable income 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 income. For a period of time following the 2014 Paladin transaction, Section 7874 of the Code precludes our U.S. affiliates from utilizing U.S. tax attributes to offset taxable income if we complete certain transactions with related non-U.S. subsidiaries. In addition, the U.S. Treasury Department has issued temporary and proposed regulations related to corporate inversions and earnings stripping. The limitations on the use of certain tax attributes and deductions in these regulations are in addition to existing rules that could impose more restrictive limitations in the event that cumulative changes in our stock ownership within a three-year period exceed certain thresholds. Such changes or the adoption of additional limitations could impact our overall utilization of deferred tax assets, potentially resulting in a material adverse impact to our financial statements and cash flows from operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

Our significant properties at December 31, 2018 are as follows:

Location (1)	Purpose	Approximate Square Footage	Ownership	Lease Term End Date
Corporate Properties:				
Dublin, Ireland	Global Corporate Headquarters	10,000	Leased	August 2024
Malvern, Pennsylvania	U.S. Corporate Headquarters	300,000	Leased (2)	December 2024
Chesterbrook, Pennsylvania	Former Auxilium Headquarters	75,000	Leased (3)	December 2023
U.S. Branded - Specialty & Established Pharmaceuticals Segment Properties:				
Cranbury, New Jersey	Manufacturing	33,000	Leased	February 2023
Rye, New York	Manufacturing	3,500	Owned	N/A
Horsham, Pennsylvania	Administration/Research & Development	40,000	Leased	July 2028
Horsham, Pennsylvania	Manufacturing	50,000	Leased	July 2028
U.S. Branded - Sterile Injectables Segment Properties:				
Rochester, Michigan	Administration/Manufacturing/Research & Development	401,000	Owned	N/A
Lansing, Michigan	Manufacturing	53,000	Leased	March 2032
U.S. Generic Pharmaceuticals Segment Properties:				
Chestnut Ridge, New York	Administration/Distribution	135,000	Owned	N/A
Chestnut Ridge, New York	Administration/Manufacturing	92,000	Owned	N/A
Chestnut Ridge, New York	Administration/Research & Development	62,000	Leased	December 2024
Chestnut Ridge, New York	Administration/Quality Assurance	40,000	Owned	N/A
Chestnut Ridge, New York	Distribution	24,000	Owned	N/A
Irvine, California	Manufacturing/Distribution	66,000	Leased	December 2022
Irvine, California	Administration/Manufacturing/Quality Assurance	41,000	Leased	December 2022
Irvine, California	Research & Development	27,000	Leased	August 2021
Montebello, New York	Distribution	190,000	Leased	January 2024
Chennai, India	Administration/Research & Development	24,000	Leased	May 2021
Chennai, India	Administration/Manufacturing	130,000	Owned	N/A
Chennai, India	Administration/Manufacturing/Research & Development	192,000	Owned	N/A
Mumbai, India	Administration/Research & Development	207,000	Leased	July 2028
Mumbai, India	Administration/Research & Development	21,000	Leased	August 2022
International Pharmaceuticals Segment Properties:				
Montreal, Canada	Paladin Headquarters	26,000	Leased	December 2023

_____

(1) Locations are categorized under the segment which they primarily support.
(2) Approximately 140,000 square feet of this property has been subleased.
(3) This property has been subleased.

Item 3. ***Legal Proceedings***

The disclosures under Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report are incorporated into this Part I, Item 3 by reference.

Item 4. ***Mine Safety Disclosures***

Not applicable.

PART II

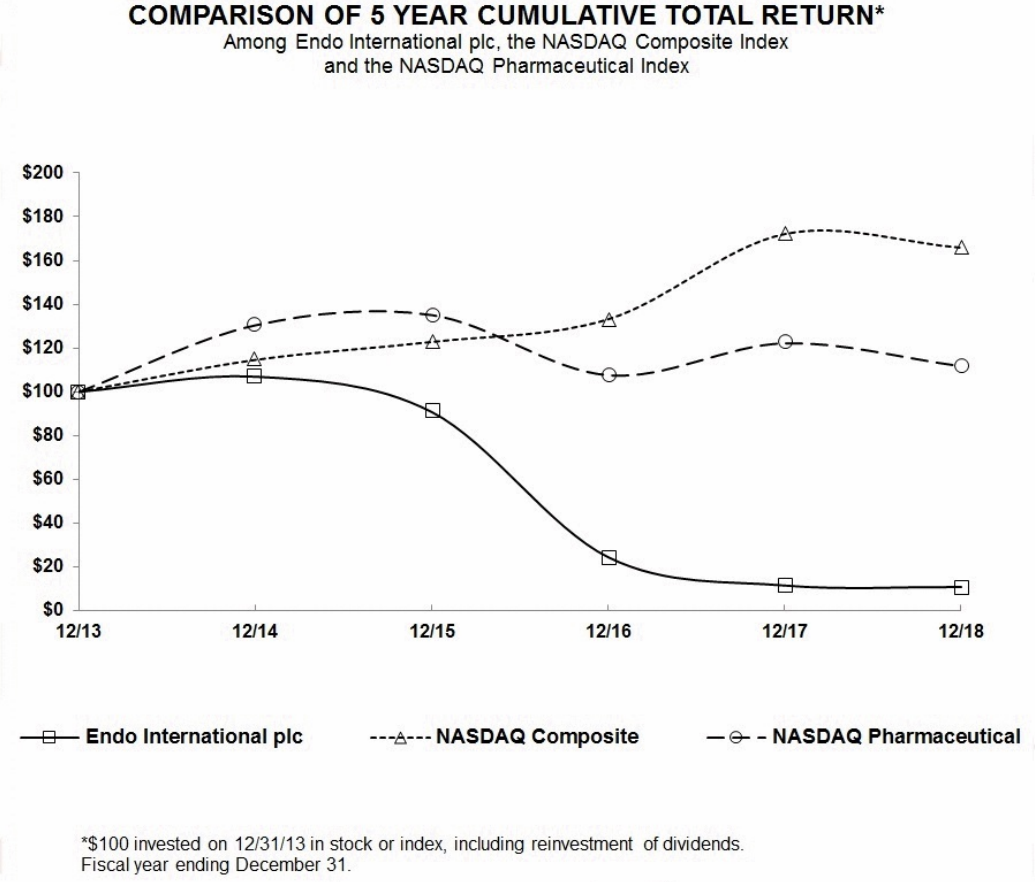
Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information. Our ordinary shares are traded on the NASDAQ under the ticker symbol "ENDP."

Holders. As of February 21, 2019, we estimate that there were approximately 76 holders of record of our ordinary shares.

Dividends. We have never declared or paid any cash dividends on our ordinary shares and we currently have no plans to declare a dividend. We are permitted to pay dividends subject to limitations imposed by Irish law, the various agreements and indentures governing our indebtedness 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 dividend. 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 pay dividends.

Performance Graph. The following graph provides a comparison of the cumulative total shareholder return on the Company's ordinary shares with that of the cumulative total shareholder return on the (i) NASDAQ Composite Index and (ii) the NASDAQ Pharmaceutical Index, commencing on December 31, 2013 and ending December 31, 2018. The graph assumes $100 invested on December 31, 2013 in the Company's ordinary shares and in each of the comparative indices. Our historic share price performance is not necessarily indicative of future share price performance.



	December 31,					
	2013	2014	2015	2016	2017	2018
Endo International plc	$ 100.00	$ 106.91	$ 90.75	$ 24.41	$ 11.49	$ 10.82
NASDAQ Composite Index	$ 100.00	$ 114.62	$ 122.81	$ 133.19	$ 172.11	$ 165.84
NASDAQ Pharmaceutical Index	$ 100.00	$ 130.42	$ 135.08	$ 107.58	$ 122.18	$ 111.73

Recent sales of unregistered securities; Use of proceeds from registered securities. There were no unregistered sales of equity securities by the Company during the three years ended December 31, 2018.

Purchase of Equity Securities by the issuer and affiliated purchasers. The following table reflects purchases of Endo International plc ordinary shares by the Company during the three months ended December 31, 2018:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plan	Approximate Dollar Value of Shares that May Yet be Purchased Under the Plan (1)
October 1, 2018 to October 31, 2018	—	—	—	$ 2,250,000,000
November 1, 2018 to November 30, 2018	—	—	—	$ 2,250,000,000
December 1, 2018 to December 31, 2018	—	—	—	$ 2,250,000,000
Three months ended December 31, 2018	—	—	—	

(1) Pursuant to Article 11 of the Company's Articles of Association, the Company has broad shareholder authority to conduct ordinary share repurchases by way of redemptions. As permitted by Irish Law and the Company's Articles of Association, any ordinary shares redeemed shall be cancelled upon redemption. The Board of Directors has approved a share buyback program (the 2015 Share Buyback Program) that authorizes the Company to redeem, in the aggregate, $2.5 billion of its outstanding ordinary shares. Redemptions under this program may be made from time to time in open market or negotiated transactions or otherwise, as determined by the Board of Directors. This program does not obligate the Company to redeem any particular amount of ordinary shares. To date, the Company 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. We currently do not intend to conduct ordinary share repurchases in the foreseeable future. Future redemptions, if any, will depend on factors such as levels of cash generation from operations, cash requirements for investment in the Company's business, repayment of future debt, if any, the then current share price, market conditions, legal limitations, sufficient distributable reserves and other factors. 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. The 2015 Share Buyback Program may be suspended, modified or discontinued at any time.

Item 6. ***Selected Financial Data***

The consolidated financial information presented below has been derived from our financial statements. The selected historical consolidated financial data presented below should be read in conjunction with Part II, Item 7 of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Part II, Item 8 of this report "Financial Statements and Supplementary Data". The selected data in this section is not intended to replace the Consolidated Financial Statements. The information presented below is not necessarily indicative of the results of our future operations.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Total revenues	$ 2,947,078	$ 3,468,858	$ 4,010,274	$ 3,268,718	$ 2,380,683
Operating (loss) income from continuing operations	(469,129)	(960,065)	(3,471,515)	(933,475)	326,482
(Loss) income from continuing operations before income tax	(938,832)	(1,483,004)	(3,923,856)	(1,437,864)	99,875
(Loss) income from continuing operations	(961,767)	(1,232,711)	(3,223,772)	(300,399)	61,608
Discontinued operations, net of tax	(69,702)	(802,722)	(123,278)	(1,194,926)	(779,792)
Consolidated net loss	(1,031,469)	(2,035,433)	(3,347,050)	(1,495,325)	(718,184)
Less: Net income (loss) attributable to noncontrolling interests	—	—	16	(283)	3,135
Net loss attributable to Endo International plc	$ (1,031,469)	$ (2,035,433)	$ (3,347,066)	$ (1,495,042)	$ (721,319)
Basic and Diluted net (loss) income per share attributable to Endo International plc:					
Continuing operations—basic	$ (4.29)	$ (5.52)	$ (14.48)	$ (1.52)	$ 0.42
Discontinued operations—basic	(0.32)	(3.60)	(0.55)	(6.07)	(5.33)
Basic	$ (4.61)	$ (9.12)	$ (15.03)	$ (7.59)	$ (4.91)
Continuing operations—diluted	$ (4.29)	$ (5.52)	$ (14.48)	$ (1.52)	$ 0.40
Discontinued operations—diluted	(0.32)	(3.60)	(0.55)	(6.07)	(5.00)
Diluted	$ (4.61)	$ (9.12)	$ (15.03)	$ (7.59)	$ (4.60)
Shares used to compute net loss per share attributable to Endo International plc—Basic	223,960	223,198	222,651	197,100	146,896
Shares used to compute net loss per share attributable to Endo International plc—Diluted	223,960	223,198	222,651	197,100	156,730
Cash dividends declared per share	$ —	$ —	$ —	$ —	$ —

	As of and for the Year Ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 1,149,113	$ 986,605	$ 517,250	$ 272,348	$ 405,696
Total assets	$ 10,132,393	$ 11,635,580	$ 14,275,109	$ 19,350,336	$ 10,824,169
Long-term debt, less current portion, net	$ 8,224,269	$ 8,242,032	$ 8,141,378	$ 8,251,657	$ 4,100,627
Other long-term obligations	$ 456,311	$ 687,759	$ 797,397	$ 1,656,391	$ 1,149,353
Total Endo International plc shareholders' (deficit) equity	$ (498,283)	$ 484,880	$ 2,701,589	$ 5,968,030	$ 2,374,757
Noncontrolling interests	$ —	$ —	$ —	$ (54)	$ 33,456
Total shareholders' (deficit) equity	$ (498,283)	$ 484,880	$ 2,701,589	$ 5,967,976	$ 2,408,213
Other Financial Data:					
Net cash provided by operating activities	$ 267,270	$ 553,985	$ 528,143	$ 118,501	$ 372,964
Net cash (used in) provided by investing activities	$ (17,900)	$ 104,583	$ (177,552)	$ (6,183,764)	$ (1,008,616)
Net cash (used in) provided by financing activities	$ (81,572)	$ (166,993)	$ (397,186)	$ 6,001,992	$ 267,669

Based on the Company's method of adoption of certain accounting principles, including its January 1, 2018 adoption of *Accounting Standards Codification Topic 606, Revenue from Contracts with Customers*, the accounting principles in effect may differ among the periods presented above.

Additionally, the Company has recorded certain charges for asset impairments and litigation-related and other matters during each year presented, portions of which are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations. The Company has completed a number of significant business combinations during or after 2014, certain of which resulted in significant financing activities. These business combinations had a significant impact on the Company's financial statements in their respective years of acquisition and in subsequent years. These impacts result from the consideration transferred by the Company for the acquisitions, the initial and subsequent purchase accounting for the acquired entities' assets and liabilities and the post-acquisition results of operations. The Company has also ceased operations and/or divested of certain businesses.

Through the dates of: (i) the sale of the HealthTronics, Inc. (HealthTronics) business in February 2014, (ii) the sale of the Men's Health and Prostate Health units of the American Medical Systems Holdings, Inc. (AMS) business in August 2015 and (iii) the wind down of the Women's Health unit of the AMS business (Astora) in March 2016, the assets and liabilities of all of these aforementioned businesses are classified as held for sale in the Consolidated Balance Sheets for all periods presented, except in the case of certain assets and liabilities that were to remain with the Company after sale including, among others, the mesh-related product liability accrual, related Qualified Settlement Funds (QSFs) and certain intangible and fixed assets. Additionally, the assets and liabilities of Litha, which was sold in July 2017, are classified as held for sale in the Consolidated Balance Sheet as of December 31, 2016. The operating results of the HealthTronics business and the entire AMS business, which includes the Men's Health, Prostate Health and Astora businesses, are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. For additional information, see Note 3. Discontinued Operations and Divestitures in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

For further information regarding the comparability of the financial data presented in the tables above and factors that may impact comparability of future results, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations as well as the Consolidated Financial Statements and related notes included in this report and previously filed Annual Reports on Form 10-K.

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

The following Management's Discussion and Analysis of Financial Condition and Results of Operations describes the principal factors affecting the results of operations, liquidity and capital resources and critical accounting estimates of Endo International plc. This discussion should be read in conjunction with our audited Consolidated Financial Statements and related notes thereto. Except for the historical information contained in this report, including the following discussion, this report contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements" beginning on page i of this report.

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

The operating results of Astora are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. For additional information, see Note 3. Discontinued Operations and Divestitures in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

EXECUTIVE SUMMARY

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

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

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

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

CRITICAL ACCOUNTING ESTIMATES

The preparation of our Consolidated Financial Statements in conformity with accounting principles generally accepted in the U.S. (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 revenue recognition, including sales deductions, financial instruments, long-lived assets, goodwill, other intangibles, income taxes, contingencies and share-based compensation, among others. Some of these estimates can be subjective and complex. Although we believe that our estimates and assumptions are reasonable, there may be other reasonable estimates or assumptions that differ significantly from ours. Further, our estimates and assumptions are based upon information available at the time they were made. Actual results may differ significantly from our estimates.

Accordingly, in order to understand our Consolidated Financial Statements, it is important to understand our critical accounting estimates. We consider an accounting estimate to be critical if the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made and changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition, results of operations or cash flows. Our most critical accounting estimates are described below.

Revenue recognition

The Company adopted *Accounting Standards Codification Topic 606, Revenue from Contracts with Customers* (ASC 606) on January 1, 2018 using the modified retrospective method for all revenue-generating contracts, including modifications thereto, that were not completed contracts at the date of adoption. For further discussion of the impact of adoption, refer to Note 2. Summary of Significant Accounting Policies in the Consolidated Financial Statements included in Part IV, Item 15 of this report. 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 revenue 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 revenue 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 revenue consists almost entirely of sales of our pharmaceutical products to customers, whereby we ship products to a customer pursuant to a purchase order. For contracts such as these, revenue 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 revenue 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, distribution service agreement and other fees for services, returns and allowances, which we collectively refer to as sales deductions. The Company 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. The variable component of the transaction price is estimated based on 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 inventory levels, current contract sales terms with our direct and indirect customers and other competitive factors. Variable consideration is included in the transaction price only to the extent that it is probable that a significant revenue reversal will not occur when the uncertainty associated with the variable consideration is resolved.

We believe that speculative buying of product, particularly in anticipation of possible price increases, has been the historical practice of certain of our customers. The timing of purchasing decisions made by wholesaler and large retail chain customers can materially affect the level of our sales in any particular period. Accordingly, our sales may not correlate to the number of prescriptions written for our products based on external third-party data.

We have entered into DSAs with certain of our significant wholesaler customers that obligate the wholesalers, in exchange for fees paid by us, to: (i) manage the variability of their purchases and inventory levels within specified limits based on product demand and (ii) provide us with specific services, including the provision of periodic retail demand information and current inventory levels for our pharmaceutical products held at their warehouse locations.

Sales deductions

As described above, the amount of revenue we recognize is equal to the fixed amount of the transaction price, adjusted for our estimates of variable consideration, including sales deductions. The impact of these sales deductions is estimated using the expected value method taking into consideration historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our direct and indirect customers and other competitive factors. We subsequently review our estimates for sales deductions based on new or revised information that becomes available to us and make revisions to our estimates if and when appropriate.

Where available, we utilize information received from our wholesaler customers about the quantities of inventory held, including the information received pursuant to DSAs, which we have not independently verified. For other customers, we have estimated inventory held based on buying patterns. In addition, we evaluate market conditions for products primarily through the analysis of wholesaler and other third party sell-through data, as well as internally-generated information, to assess factors that could impact expected product demand at the estimate date. As of December 31, 2018, we believe that our estimates of the level of inventory held by our customers is within a reasonable range as compared to both historical amounts and expected demand for each respective product.

If the assumptions we use to calculate our estimates for sales deductions do not appropriately reflect future activity, our financial position, results of operations and cash flows could be materially impacted. The following table presents the activity and ending balances, excluding Discontinued operations, for our product sales provisions for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	Returns and Allowances	Rebates	Chargebacks	Other Sales Deductions	Total
Balance, January 1, 2016	$ 356,932	$ 823,157	$ 379,216	$ 46,802	$ 1,606,107
Current year provision	122,414	1,562,340	3,125,109	332,721	5,142,584
Prior year provision	(7,199)	(18,705)	4,707	311	(20,886)
Payments or credits	(139,396)	(1,878,602)	(3,162,423)	(312,829)	(5,493,250)
Balance, December 31, 2016	$ 332,751	$ 488,190	$ 346,609	$ 67,005	$ 1,234,555
Current year provision	108,544	1,315,012	2,659,421	242,343	4,325,320
Prior year provision	(2,028)	(21,442)	1,224	(269)	(22,515)
Payments or credits	(147,100)	(1,427,073)	(2,750,546)	(268,731)	(4,593,450)
Decreases due to business dispositions	(1,133)	—	—	—	(1,133)
Balance, December 31, 2017	$ 291,034	$ 354,687	$ 256,708	$ 40,348	$ 942,777
Current year provision	78,767	912,885	2,268,212	161,788	3,421,652
Prior year provision	3,693	(1,053)	785	(664)	2,761
Payments or credits	(136,548)	(986,803)	(2,307,339)	(164,169)	(3,594,859)
Balance, December 31, 2018	$ 236,946	$ 279,716	$ 218,366	$ 37,303	$ 772,331

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. The primary factors we consider in estimating our potential product returns include:

- the shelf life or expiration date of each product;
- historical levels of expired product returns;
- external data with respect to inventory levels in the wholesale distribution channel;
- external data with respect to prescription demand for our products; and
- the estimated returns liability to be processed by year of sale based on analysis of lot information related to actual historical returns.

In determining our estimates for returns and allowances, we are required to make certain assumptions regarding the timing of the introduction of new products and the potential of these products to capture market share. In addition, we make certain assumptions with respect to the extent and pattern of decline associated with generic competition. To make these assessments, we utilize market data for similar products as analogs for our estimations. We use our best judgment to formulate these assumptions based on past experience and information available to us at the time. We continually reassess and make appropriate changes to our estimates and assumptions as new information becomes available to us.

Our estimate for returns and allowances may be impacted by a number of factors, but the principal factor relates to the level of inventory in the distribution channel. When we are aware of an increase in the level of inventory of our products in the distribution channel, we consider the reasons for the increase to determine whether we believe the increase is temporary or other-than-temporary. Increases in inventory levels assessed as temporary will not result in an adjustment to our provision for returns and allowances. Some of the factors that may be an indication that an increase in inventory levels will be temporary include:

- recently implemented or announced price increases for our products; and
- new product launches or expanded indications for our existing products.

Conversely, other-than-temporary increases in inventory levels may be an indication that future product returns could be higher than originally anticipated and, accordingly, we may need to adjust our provision for returns and allowances. Some of the factors that may be an indication that an increase in inventory levels will be other-than-temporary include:

- declining sales trends based on prescription demand;
- recent regulatory approvals to shorten the shelf life of our products, which could result in a period of higher returns related to older product still in the distribution channel;
- introduction of new product or generic competition;

- increasing price competition from generic competitors; and
- changes to the National Drug Codes (NDCs) of our products, which could result in a period of higher returns related to product with the old NDC, as our customers generally permit only one NDC per product for identification and tracking within their inventory systems.

Rebates

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

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

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

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

We participate in various federal and state government-managed programs whereby discounts and rebates are provided to participating government entities. For example, Medicaid rebates are amounts owed based upon contractual agreements or legal requirements with public sector (Medicaid) benefit providers after the final dispensing of the product by a pharmacy to a benefit plan participant. Medicaid reserves are based on expected payments, which are driven by patient usage, contract performance and field inventory that will be subject to a Medicaid rebate. Medicaid rebates are typically billed up to 180 days after the product is shipped, but can be as much as 270 days after the quarter in which the product is dispensed to the Medicaid participant. In addition to the estimates mentioned above, our calculation also requires other estimates, such as estimates of sales mix, to determine which sales are subject to rebates and the amount of such rebates. Periodically, we adjust the Medicaid rebate provision based on actual claims paid. Due to the delay in billing, adjustments to actual claims paid may incorporate revisions of this provision for several periods. Because Medicaid pricing programs involve particularly difficult interpretations of complex statutes and regulatory guidance, our estimates could differ from actual experience.

In determining our estimates for rebates, we consider the terms of our contracts, relevant statutes, historical relationships of rebates to revenues, past payment experience, estimated inventory levels of our customers and estimated future trends. Our provisions for rebates include estimates for both unbilled claims for end-customer sales that have already occurred and future claims that will be made when inventory in the distribution channel is sold through to end-customer plan participants. Changes in the level of utilization of our products through private or public benefit plans and group purchasing organizations will affect the amount of rebates that we owe.

Chargebacks

We market and sell products to both: (i) direct customers including wholesalers, distributors, warehousing pharmacy chains and other direct purchasing groups and (ii) indirect customers including independent pharmacies, non-warehousing chains, managed-care organizations, group purchasing organizations and government entities. We enter into agreements with certain of our indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price. Such credit is called a chargeback.

Our provision for chargebacks consists of our estimates for the credits described above. The primary factors we consider in developing and evaluating our provision for chargebacks include:

- the average historical chargeback credits;
- estimated future sales trends; and
- an estimate of the inventory held by our wholesalers, based on internal analysis of a wholesaler's historical purchases and contract sales.

Other sales deductions

We offer certain of our customers prompt pay cash discounts. Provisions for prompt pay discounts are estimated and recorded at the time of sale. We estimate provisions for cash discounts based on contractual sales terms with customers, an analysis of unpaid invoices and historical payment experience. Estimated cash discounts have historically been predictable and less subjective due to the limited number of assumptions involved, the consistency of historical experience and the fact that we generally settle these amounts within 30 to 60 days.

Shelf-stock adjustments are credits issued to our customers to reflect decreases in the selling prices of our products. These credits are customary in the industry and are intended to reduce a customer's inventory cost to better reflect current market prices. The determination to grant a shelf-stock credit to a customer following a price decrease is generally at our discretion, rather than contractually required. The primary factors we consider when deciding whether to record a reserve for a shelf-stock adjustment include:

- the estimated number of competing products being launched as well as the expected launch date, which we determine based on market intelligence;
- the estimated decline in the market price of our product, which we determine based on historical experience and customer input; and
- the estimated levels of inventory held by our customers at the time of the anticipated decrease in market price, which we determine based upon historical experience and customer input.

Valuation of long-lived assets

As of December 31, 2018, our combined long-lived assets balance, including property, plant and equipment and finite-lived intangible assets, is approximately $3.9 billion.

Long-lived 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 Statements of Operations in the period that the impairment occurs. As a result of the significance of our long-lived assets, any recognized impairment loss could have a material adverse impact on our financial position and results of operations.

Our reviews of long-lived assets during the three years ended December 31, 2018 resulted in certain impairment charges. The majority of these charges related to finite-lived intangible assets, which are described in Note 10. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report. Our impairment charges relating to long-lived assets were generally based on fair value estimates determined using either discounted cash flow models or offers from prospective buyers. When testing a long-lived asset using a discounted cash flow model, we utilize assumptions related to the revenues, growth rates and operating margins of the corresponding product based on management's annual and ongoing budgeting, forecasting and planning processes, which represent our best estimate of future cash flows. These estimates are subject to the economic environment in which our segments operate, demand for our products and competitor actions. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions would increase or decrease our estimated discounted future cash flows, the resulting estimated fair values and the amounts of our related impairments, if any. The discount rates applied to intangible long-lived assets impaired in 2018 ranged from 9.0% to 10.0%.

Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant under-performance of a product line in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in our use of the assets.

Our long-lived intangible assets, which consist of license rights and developed technology, are initially recorded at fair value upon acquisition. To the extent they are deemed to have finite lives, they are then amortized over their estimated useful lives using either the straight-line method or, in the case of certain developed technology assets, the economic benefit model. The values of these various assets are subject to continuing scientific, medical and marketplace uncertainty. Factors giving rise to our initial estimate of useful lives are subject to change. Significant changes to any of these factors may result in a reduction in the useful lives of the assets and acceleration of related amortization expense, which could cause our operating income, net income and net income per share to decrease. Amortization expense is not recorded on assets held for sale. Each category of long-lived intangible assets is described further below.

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

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

Goodwill and indefinite-lived intangible assets

As of December 31, 2018, our combined goodwill and indefinite-lived intangible assets balance is approximately $3.9 billion.

We test goodwill and indefinite-lived intangible assets for impairment at least annually, but also perform tests whenever events or changes in circumstances indicate that the assets might be impaired. Our annual assessment is performed as of October 1st.

Following our early adoption, effective January 1, 2017, of Accounting Standards Update (ASU) No. 2017-04, *"Intangibles - Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment"* (ASU 2017-04), we perform our goodwill impairment tests by comparing the fair value and carrying amount of each of our reporting units. Any goodwill impairment charge we recognize for a reporting unit is equal to the lesser of (i) the total goodwill allocated to that reporting unit and (ii) the amount by which that reporting unit's carrying amount exceeds its fair value.

Similarly, we perform our indefinite-lived intangible asset impairment tests by comparing the fair value of each intangible asset with its carrying amount. If the carrying amount of an indefinite-lived intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess.

The fair values of our reporting units and of identified indefinite-lived intangible assets are determined using an income approach that utilizes a discounted cash flow model, or, where appropriate, a market approach, or a combination thereof. The discounted cash flow models are dependent upon our estimates of future cash flows and other factors. Our estimates of future cash flows involve assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions, all which may differ from actual future cash flows.

Assumptions related to future operating performance are based on management's annual and ongoing budgeting, forecasting and planning processes and represent our best estimate of the future results of operations as of a point in time. These estimates are subject to many assumptions, such as the economic environment in which our segments operate, demand for our products, competitor actions and factors which could affect our tax rate. Estimated future pre-tax cash flows are adjusted for taxes using a market participant tax rate and discounted to present value using a market participant, weighted average cost of capital. Financial and credit market volatility directly impacts certain inputs and assumptions used to develop the weighted average cost of capital such as the risk-free interest rate, industry beta, debt interest rate and our market capital structure. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions would increase or decrease our estimated discounted future cash flows, the resulting estimated fair values and the amounts of our related impairments, if any.

In order to assess the reasonableness of the calculated fair values of our reporting units, we also compare the sum of the reporting units' fair values to Endo's market capitalization and calculate an implied control premium (the excess sum of the reporting units' fair values over the market capitalization) or an implied control discount (the excess sum of total invested capital over the sum of the reporting units' fair values). The Company evaluates the implied control premium or discount by comparing it to control premiums or discounts of recent comparable market transactions, as applicable. If the control premium or discount is not reasonable in light of comparable recent transactions, or recent movements in the Company's share price, we reevaluate the fair value estimates of the reporting units by adjusting discount rates and/or other assumptions. This re-evaluation could correlate to different implied fair values for certain or all of the Company's reporting units.

Our first quarter 2018 change in segments described in Note 6. Segment Results in the Consolidated Financial Statements included in Part IV, Item 15 of this report resulted in changes to our reporting units for goodwill impairment testing purposes, including the creation of a new U.S. Branded - Sterile Injectables reporting unit, which was previously part of our Generics reporting unit. As a result of these changes, under U.S. GAAP, we tested the goodwill of the former Generics reporting unit immediately before the segment realignment and the goodwill of both the new U.S. Branded - Sterile Injectables and U.S. Generic Pharmaceuticals reporting units immediately after the segment realignment. The critical accounting estimates used in connection with these tests are discussed below and a description of goodwill impairment charges is included in Note 10. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

As a result of the forgoing changes and the resulting goodwill impairment tests performed during the three months ended March 31, 2018, we recorded a pre-tax, non-cash goodwill impairment charge relating to our new U.S. Generic Pharmaceuticals reporting unit of $391.0 million. A 50 basis point increase in the assumed discount rate used in the impairment test would have increased this goodwill impairment charge by approximately $60 million. Additionally, with respect to the first quarter 2018 goodwill impairment tests performed related to our former Generics and new U.S. Branded - Sterile Injectables reporting units, which did not result in impairment charges, a 50 basis point increase in the assumed discount rates would not have changed the results of these tests.

Endo subsequently performed its annual goodwill and indefinite-lived intangible assets impairment test as of October 1, 2018. For the purpose of the 2018 annual test, the Company had four reporting units with goodwill: (1) U.S. Branded - Specialty & Established Pharmaceuticals, (2) U.S. Branded - Sterile Injectables, (3) U.S. Generic Pharmaceuticals and (4) Paladin. The fair values of each of our reporting units and associated indefinite-lived intangible assets were determined using an income approach with discount rates ranging from 9.5% to 11.5%, 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. As a result of the 2018 annual test, the Company recorded pre-tax non-cash goodwill impairment charges of $258.0 million and $31.0 million related to its U.S. Generic Pharmaceuticals and Paladin reporting units, respectively.

A 50 basis point increase in the assumed discount rate utilized in each test would have increased our U.S. Generic Pharmaceuticals reporting unit goodwill impairment charge by approximately $40 million and our Paladin reporting unit goodwill impairment charge by approximately $7 million.

We did not record goodwill impairment charges for the other reporting units as a result of the annual tests. An increase of 50 basis points to our assumed discount rates used in testing the U.S. Branded - Specialty & Established Pharmaceuticals and the U.S. Branded - Sterile Injectables reporting units would not have changed the results of the 2018 annual tests.

Income taxes

Our income tax expense, deferred tax assets and liabilities, income tax payable and reserves for unrecognized tax benefits reflect our best assessment of estimated current and future taxes to be paid. We are subject to income taxes in the U.S. and numerous other foreign jurisdictions in which we operate. Significant judgments and estimates are required in determining the consolidated income tax expense or benefit for financial statement purposes. Deferred income taxes arise from temporary differences, which result in future taxable or deductible amounts, between the tax basis of assets and liabilities and the corresponding amounts reported in our Consolidated Financial Statements. In assessing the ability to realize deferred tax assets, we consider, when appropriate, future taxable income by tax jurisdiction and tax planning strategies. Where appropriate, we record a valuation allowance to reduce our deferred tax assets to equal an amount that is more likely than not to be realized. In projecting future taxable income, we begin with historical results, which are in certain cases adjusted for the results of discontinued operations, changes in tax laws or nonrecurring transactions. We incorporate assumptions about the amount of future earnings within a specific jurisdiction's pretax operating income, adjusted for material changes including in business operations. The assumptions about future taxable income require significant judgment and, while these assumptions rely heavily on estimates, such estimates are consistent with the plans we are using to manage the underlying businesses.

Future changes in tax laws and rates could also affect recorded deferred tax assets and liabilities, including further administrative or regulatory guidance related to the TCJA. Any adjustments to these estimates will be recorded as an income tax expense or benefit in the period the adjustment is determined.

The calculation of our tax liabilities often involves dealing with uncertainties in the application of complex tax laws and regulations in a multitude of jurisdictions across our global operations. A benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained on the basis of the technical merits upon examination, including resolutions of any related appeals or litigation processes. We first record unrecognized tax benefits as liabilities and then adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available at the time of establishing the liability. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment, potentially including interest and penalties, that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information becomes available. We classify interest and penalties arising from uncertain tax positions as a component of tax expense.

We make an evaluation at the end of each reporting period as to whether or not some or all of the undistributed earnings of our subsidiaries are indefinitely reinvested. While we may have concluded in the past that some of such undistributed earnings are indefinitely reinvested, facts and circumstances may change in the future. Changes in facts and circumstances may include a change in the estimated capital needs of our subsidiaries, or a change in our corporate liquidity requirements. Such changes could result in our management determining that some or all of such undistributed earnings are no longer indefinitely reinvested. In that event, we would be required to adjust our income tax provision in the period we determined that the earnings will no longer be indefinitely reinvested outside the relevant tax jurisdiction.

Contingencies

The Company is subject to various patent challenges, product liability claims, government investigations and other legal proceedings in the ordinary course of business. Material legal proceedings are discussed in Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report. Contingent accruals and legal settlements are recorded in the Consolidated Statements of Operations as Litigation-related and other contingencies, net (or Discontinued operations, net in the case of vaginal mesh matters) when the Company 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 Statements of Operations (or Discontinued operations, net 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 factors we consider in developing our liabilities for legal proceedings include the merits and jurisdiction of the proceeding, the nature and the number of other similar current and past proceedings, the nature of the product and the current assessment of the science subject to the proceeding, if applicable, and the likelihood of the conditions of settlement being met.

In order to evaluate whether a claim is probable of loss, we may rely on certain information about the claim. Without access to and review of such information, we may not be in a position to determine whether a loss is probable. Further, the timing and extent to which we obtain any such information, and our evaluation thereof, is often impacted by items outside of our control including, without limitation, the normal cadence of the litigation process and the provision of claim information to us by plaintiff's counsel. The amount of our liabilities for legal proceedings may change as we receive additional information and/or become aware of additional asserted or unasserted claims. Additionally, there is a possibility that we will suffer adverse decisions or verdicts of substantial amounts or that we will enter into additional monetary settlements, either of which could be in excess of amounts previously accrued for. Any changes to our liabilities for legal proceedings could have a material adverse effect on our business, financial condition, results of operations and cash flows.

As of December 31, 2018, our reserve for loss contingencies totaled $905.1 million, of which $748.6 million relates to our liability accrual for vaginal mesh cases and other mesh-related matters. Although we believe there is a reasonable possibility that a loss in excess of the amount recognized exists, we are unable to estimate the possible loss or range of loss in excess of the amount recognized at this time.

RESULTS OF OPERATIONS

Consolidated Results Review

The following table displays our revenue, gross margin, gross margin percentage and other pre-tax expense or income for the years ended December 31, 2018, 2017 and 2016 (dollars in thousands):

				% Change	
	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Total revenues	$ 2,947,078	$ 3,468,858	$ 4,010,274	(15)%	(14)%
Cost of revenues	1,631,682	2,228,530	2,634,973	(27)%	(15)%
Gross margin	$ 1,315,396	$ 1,240,328	$ 1,375,301	6 %	(10)%
Gross margin percentage	*44.6%*	*35.8%*	*34.3%*		
Selling, general and administrative	646,037	629,874	770,728	3 %	(18)%
Research and development	185,826	172,067	183,372	8 %	(6)%
Litigation-related and other contingencies, net	13,809	185,990	23,950	(93)%	NM
Asset impairment charges	916,939	1,154,376	3,781,165	(21)%	(69)%
Acquisition-related and integration items	21,914	58,086	87,601	(62)%	(34)%
Interest expense, net	521,656	488,228	452,679	7 %	8 %
Loss on extinguishment of debt	—	51,734	—	(100)%	NM
Other income, net	(51,953)	(17,023)	(338)	NM	NM
Loss from continuing operations before income tax	$ (938,832)	$ (1,483,004)	$ (3,923,856)	(37)%	(62)%

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

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

In 2017, total revenues decreased primarily due to declines in our U.S. Generic Pharmaceuticals segment's product portfolio, driven by overall market trends and product rationalization, and our U.S. Branded - Specialty & Established Pharmaceuticals segment's Established Products portfolio, driven by the impact of generic competition, the divestiture of STENDRA® in the third quarter of 2016 and actions taken with respect to the voluntary withdrawal of OPANA® ER that are further described below. Additionally, sales in our International Pharmaceuticals segment were negatively impacted by our divestitures of Litha and Somar in the second half of 2017. These declines were partially offset by continued strong performance from our U.S. Branded - Sterile Injectables segment, including VASOSTRICT® and ADRENALIN®, and our U.S. Branded - Specialty & Established Pharmaceuticals segment's Specialty Products portfolio, which includes XIAFLEX®.

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

Cost of revenues and gross margin percentage. During the years ended December 31, 2018, 2017 and 2016, we incurred certain charges that impact the comparability of total Cost of revenues, including, among others, those related to acquisitions, separation benefits and restructurings initiatives. The following table summarizes such amounts (in thousands):

	2018	2017	2016
Amortization of intangible assets (1)	$ 622,339	$ 773,766	$ 876,451
Inventory step-up and certain manufacturing costs that will be eliminated pursuant to integration plans	$ 261	$ 390	$ 124,349
Separation benefits and other cost reduction initiatives (2)	$ 60,434	$ 175,809	$ 53,133

_____

(1) Amortization expense fluctuates based on changes in the total amount of amortizable intangible assets and the rate of amortization in effect for each intangible asset, both of which can vary based on factors such as the amount and timing of acquisitions, dispositions, asset impairment charges, transfers between indefinite- and finite-lived intangibles assets, changes in foreign currency rates and changes in the composition of our intangible assets impacting the weighted average useful lives and amortization methodologies being utilized. The decrease in 2018 was primarily driven by the impact of 2017 amortization expense for both ezetimibe tablets and quetiapine ER tablets, which were fully amortized prior to January 1, 2018, the impact of asset impairment charges and decreases in the rate of amortization expense for certain assets, partially offset by the impact of certain in-process research and development assets put into service. The decrease in 2017 was primarily driven by our divestitures of Litha and Somar in the second half of 2017, decreases in the rate of amortization expense for certain assets and the impact of asset impairment charges. This decrease was partially offset by the impact of amortization expense for ezetimibe tablets, which launched in the fourth quarter of 2016, and certain in-process research and development assets put into service.

(2) Amounts primarily relate to certain employee separation costs, accelerated depreciation charges, charges to increase excess inventory reserves related to restructurings and other cost reduction and restructuring charges. See Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report for discussion of our material restructuring initiatives.

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

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

In 2017, Cost of revenues decreased primarily due to the previously described decrease in total revenues, a decrease to inventory step-up expense based on the timing of prior acquisitions and a decrease to amortization expense. These savings were partially offset by increased restructuring charges included in Cost of revenues.

Gross margin percentage increased in 2017 primarily due to the favorable margin impact of product rationalization efforts and changes in the mix of total revenues, including a shift from generic to branded products. This increase was partially offset by the margin effects of continued competitive pressure on the commoditized generic products in our U.S. Generic Pharmaceuticals segment.

Our material restructuring initiatives are described more fully in Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

In 2017, Selling, general and administrative expenses decreased primarily as a result of cost reductions that were implemented during 2016 and in the first half of 2017, including the impact of those related to various restructuring initiatives. Additionally, there was a decrease in restructuring charges included in Selling, general and administrative expense in 2017.

Our material restructuring initiatives and material legal proceedings and other contingent matters are described in more detail in Note 4. Restructuring and Note 15. Commitments and Contingencies, respectively, in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

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

During the second quarter of 2018, we entered into a development, license and commercialization agreement related to five sterile injectable product candidates, at which time we became obligated to make an upfront payment, which was recorded as Research and development expense in the Consolidated Statements of Operations. This agreement is described more fully in Note 11. License and Collaboration Agreements in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

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

In 2017, R&D expense decreased due to a reduction in costs associated with post-marketing studies related to certain products in our U.S. Branded - Specialty & Established Pharmaceuticals segment and our previous Phase 2b cellulite trial, the results of which were announced in November 2016, cost savings resulting from the January 2017 Restructuring Initiative and lower development costs and filing fees related to new product launches in our U.S. Generic Pharmaceuticals segment. Partially offsetting the decrease were preliminary costs incurred in 2017 associated with the Phase 3 cellulite trials described above.

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

Our material restructuring initiatives are described more fully in Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Litigation-related and other contingencies, net. Included within Litigation-related and other contingencies, net are changes to our accruals for litigation-related settlement charges and certain settlements proceeds related to suits filed by our subsidiaries. Our material legal proceedings and other contingent matters are described in more detail in Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Asset impairment charges. The following table presents the components of our total Asset impairment charges for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Goodwill impairment charges	$ 680,000	$ 288,745	$ 2,676,350
Other intangible asset impairment charges	230,418	799,955	1,088,903
Property, plant and equipment impairment charges	6,521	65,676	15,912
Total asset impairment charges	$ 916,939	$ 1,154,376	$ 3,781,165

A discussion of our impairment testing methodology and the critical accounting estimates made in connection with our various impairment tests is included above under the caption "CRITICAL ACCOUNTING ESTIMATES." The factors leading to our material asset impairment tests, as well as the results of these tests, are further described in Note 9. Property, Plant and Equipment and Note 10. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Acquisition-related and integration items. The following table presents the components of our total Acquisition-related and integration items for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Net expense from changes in the fair value of acquisition-related contingent consideration	$ 19,910	$ 49,949	$ 23,823
Other	2,004	8,137	63,778
Acquisition-related and integration items	$ 21,914	$ 58,086	$ 87,601

Net expense from changes in the fair value of acquisition-related contingent consideration resulted primarily from changes to our estimates regarding the timing and amount of the future revenues of the underlying products and changes in other assumptions impacting the probability of, and extent to which we will incur related contingent obligations. See Note 7. Fair Value Measurements in the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion of our acquisition-related contingent consideration.

The decreases in other Acquisition-related and integration items in both 2018 and 2017 were primarily attributable to the timing of prior acquisitions and the associated costs. In 2016, amounts primarily relate to costs associated with integrating our January 2015 acquisition of Auxilium Pharmaceuticals, Inc. (subsequently converted to Auxilium Pharmaceuticals, LLC and hereinafter referred to as Auxilium) and our September 2015 acquisition of Par Pharmaceutical Holdings, Inc (Par), which costs did not reoccur to the same extent in 2017.

Interest expense, net. The components of Interest expense, net for the years ended December 31, 2018, 2017 and 2016 are as follows (in thousands):

	2018	2017	2016
Interest expense	$ 534,850	$ 494,694	$ 456,396
Interest income	(13,194)	(6,466)	(3,717)
Interest expense, net	$ 521,656	$ 488,228	$ 452,679

The increase in interest expense in 2018 was primarily attributable to increased interest rates, including the effects of both increases in LIBOR, which impacted our variable-rate debt, and the refinancing that occurred on April 27, 2017, which is further described in Note 14. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report. Although we cannot predict future interest rates with certainty, absent any actions to reduce the principal amount of our debt, interest expense is likely to increase in 2019 as a result of recent and potential future increases in LIBOR. In 2017, the increase in interest expense was primarily due to increased interest rates following the refinancing that occurred on April 27, 2017.

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

Loss on extinguishment of debt. Loss on extinguishment of debt in 2017 related to certain previously unamortized debt issuance costs that were charged to expense in connection with the April 2017 refinancing. There were no comparable charges in 2018 or 2016.

Other income, net. The components of Other income, net for the years ended December 31, 2018, 2017 and 2016 are as follows (in thousands):

	2018	2017	2016
Net (gain) loss on sale of business and other assets	$ (45,155)	$ (13,809)	$ 3,192
Foreign currency (gain) loss, net	(3,762)	(2,801)	2,991
Net loss (gain) from our investments in the equity of other companies	3,444	898	(1,190)
Other miscellaneous, net	(6,480)	(1,311)	(5,331)
Other income, net	$ (51,953)	$ (17,023)	$ (338)

In 2018, Net (gain) loss on sale of business and other assets primarily relates to proceeds received from the 2018 sales of various ANDAs and of the Huntsville facilities, as further discussed in Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

In 2017, Net (gain) loss on sale of business and other assets includes a $10.1 million gain resulting from the sale of Litha, as further described in Note 3. Discontinued Operations and Divestitures in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

Income tax expense (benefit). The following table displays our Loss from continuing operations before income tax, Income tax expense (benefit) and effective tax rate for the years ended December 31, 2018, 2017 and 2016 (dollars in thousands):

	2018	2017	2016
Loss from continuing operations before income tax	$ (938,832)	$ (1,483,004)	$ (3,923,856)
Income tax expense (benefit)	$ 22,935	$ (250,293)	$ (700,084)
Effective tax rate	*(2.4)%*	*16.9%*	*17.8%*

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 income or loss in those various jurisdictions. It is also impacted by certain items that may occur in any given period, but are not consistent from period to period.

The tax expense in 2018 primarily related to the establishment of a valuation allowance against certain U.S. deferred tax assets. The following items had the most significant impact on the difference between the notional U.S. statutory federal income tax rate and our effective tax rate in 2017 and 2016:

2017:

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

2016:

- $926.9 million tax expense or a 23.6% rate charge resulting from the non-deductible portion of impaired goodwill.
- $762.6 million tax expense or a 19.4% rate charge from recording net valuation allowances relating to the Company's operations.
- $636.1 million net tax benefit or a 16.2% rate benefit associated with the recognition of outside basis differences in certain subsidiaries.
- $301.7 million net tax benefit or a 7.7% rate benefit associated with our geographical mix of earnings. As of December 31, 2016, no provision has been made for Irish taxes, as the majority of our undistributed earnings were considered to be permanently reinvested outside of Ireland.

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

The Internal Revenue Service (IRS) presently is examining certain of our subsidiaries' U.S. income tax returns for fiscal years ending between December 31, 2011 and December 31, 2015 and, in connection with those examinations, is reviewing our tax positions related to, among other things, certain intercompany arrangements, including the level of profit earned by our United States subsidiaries pursuant to such arrangements, and a worthless stock deduction directly attributable to product liability losses. The IRS may examine our tax returns for other fiscal years and/or for other tax positions. Similarly, other tax authorities may examine our non-U.S. tax returns and propose adjustments to our taxes. Such examinations may lead to proposed or actual adjustments to our taxes that may be material, individually or in the aggregate. An adverse outcome of these tax examinations could have a material adverse effect on our business, financial position, results of operations and growth prospects. See the risk factor "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 Part I, Item 1A of this document for more information.

For additional information on our income taxes, see Note 20. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Discontinued operations, net of tax. As further described in Note 3. Discontinued Operations and Divestitures in the Consolidated Financial Statements included in Part IV, Item 15 of this report, the operating results of Astora are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. The results of our discontinued operations, net of tax, were losses of $69.7 million, $802.7 million and $123.3 million, during the years ended December 31, 2018, 2017 and 2016, respectively.

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

In 2017, the primary driver of the change was the after-tax impact of the 2017 charge discussed above. This compares to $20.1 million of litigation-related charges recorded during 2016. Also contributing to the change was a decrease in revenue resulting from the wind-down of our Astora business in 2016. Partially offsetting these changes was an overall decrease in spending in 2017, as well as a decrease in asset impairment charges of $21.3 million.

For further discussion of mesh-related matters, refer to Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Key Trends. We estimate that the following factors will impact our 2019 total revenues as compared to 2018:

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

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

Business Segment Results Review

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

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

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

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

There are limitations to using financial measures such as adjusted income from continuing operations before income tax. Other companies in our industry may define adjusted income from continuing operations before income tax differently than we do. As a result, it may be difficult to use adjusted income from continuing operations before income tax or similarly named adjusted financial measures that other companies may use to compare the performance of those companies to our performance. Because of these limitations, adjusted income 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 income, cash flows or any other financial measure determined in accordance with U.S. GAAP. We compensate for these limitations by providing reconciliations of our total segment adjusted income from continuing operations before income tax to our consolidated Loss from continuing operations before income tax, which is determined in accordance with U.S. GAAP and included in our Consolidated Statements of Operations.

Revenues. The following table displays our revenue by reportable segment for the years ended December 31, 2018, 2017 and 2016 (dollars in thousands):

				% Change	
	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
U.S. Branded - Specialty & Established Pharmaceuticals	$ 862,832	$ 957,525	$ 1,166,294	(10)%	(18)%
U.S. Branded - Sterile Injectables	929,566	750,471	576,399	24 %	30 %
U.S. Generic Pharmaceuticals	1,012,215	1,530,530	1,988,214	(34)%	(23)%
International Pharmaceuticals (1)	142,465	230,332	279,367	(38)%	(18)%
Total net revenues from external customers	$ 2,947,078	$ 3,468,858	$ 4,010,274	(15)%	(14)%

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

U.S. Branded - Specialty & Established Pharmaceuticals. The following table displays the significant components of our U.S. Branded - Specialty & Established Pharmaceuticals revenues from external customers for the years ended December 31, 2018, 2017 and 2016 (dollars in thousands):

				% Change	
	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Specialty Products:					
XIAFLEX®	$ 264,638	$ 213,378	$ 189,689	24 %	12 %
SUPPRELIN® LA	81,707	86,211	78,648	(5)%	10 %
Other Specialty (1)	156,607	153,384	138,483	2 %	11 %
Total Specialty Products	$ 502,952	$ 452,973	$ 406,820	11 %	11 %
Established Products:					
PERCOCET®	$ 122,901	$ 125,231	$ 139,211	(2)%	(10)%
VOLTAREN® Gel	57,700	68,780	100,642	(16)%	(32)%
OPANA® ER	—	83,826	158,938	(100)%	(47)%
Other Established (2)	179,279	226,715	360,683	(21)%	(37)%
Total Established Products	$ 359,880	$ 504,552	$ 759,474	(29)%	(34)%
Total U.S. Branded - Specialty & Established Pharmaceuticals (3)	$ 862,832	$ 957,525	$ 1,166,294	(10)%	(18)%

(1) Products included within Other Specialty include NASCOBAL® Nasal Spray, TESTOPEL® and AVEED®.
(2) Products included within Other Established include, but are not limited to, LIDODERM®, FORTESTA® Gel, EDEX® and TESTIM® including the authorized generics of TESTIM® and FORTESTA® Gel.
(3) Individual products presented above represent the top two performing products in each product category and/or any product having revenues in excess of $100 million during any of the years ended December 31, 2018, 2017 and 2016 or $25 million during any quarterly period in 2018.

Specialty Products

The increases in net sales of XIAFLEX® in both 2018 and 2017 were primarily attributable to demand growth driven by the continued investment and promotional efforts behind XIAFLEX®, as well as price.

The decrease in net sales of SUPPRELIN® LA in 2018 was primarily attributable to decreased volume. The increase in 2017 was primarily attributable to price.

The increase in net sales of Other Specialty Products in 2018 was primarily attributable to increased sales of NASCOBAL® Nasal Spray and AVEED® due to improved volume. The increases in these products were partially offset by lower sales of TESTOPEL® due to decreases in both volume and price. Net sales of Other Specialty Products increased in 2017, driven by increased net sales of NASCOBAL® Nasal Spray, AVEED® and TESTOPEL®, which all benefited from increased prices. NASCOBAL® Nasal Spray and AVEED® also benefited from improved volume.

Established Products

The decreases in net sales of PERCOCET® in both 2018 and 2017 were primarily attributable to volume decreases, partially offset by price increases.

The decreases in net sales of VOLTAREN® Gel for both 2018 and 2017 were primarily attributable to price and volume decreases as a result of ongoing competitive pressure from generic competition. To the extent additional competitors launch generic versions of VOLTAREN® Gel, our revenues could decline further.

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

Net sales of Other Established Products for both 2018 and 2017 were negatively impacted by volume decreases resulting from generic competition and certain other factors, including a decrease in 2017 resulting from the divestiture of STENDRA® in the third quarter of 2016.

U.S. Branded - Sterile Injectables. The following table displays the significant components of our U.S. Branded - Sterile Injectables revenues from external customers for the years ended December 31, 2018, 2017 and 2016 (dollars in thousands):

				% Change	
	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
VASOSTRICT®	$ 453,767	$ 399,909	$ 343,468	13%	16%
ADRENALIN®	143,489	76,523	22,172	88%	NM
Ertapenem for injection	57,668	—	—	NM	NM
Other Sterile Injectables (1)	274,642	274,039	210,759	—%	30%
Total U.S. Branded - Sterile Injectables (2)	$ 929,566	$ 750,471	$ 576,399	24%	30%

_____
NM indicates that the percentage change is not meaningful or is greater than 100%.
(1) Products included within Other Sterile Injectables include, but are not limited to, APLISOL® and ephedrine sulfate injection.
(2) Individual products presented above represent the top two performing products for this segment and/or any product having revenues in excess of $100 million during any of the years ended December 31, 2018, 2017 and 2016 or $25 million during any quarterly period in 2018.

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

We are aware of certain competitive actions taken by other pharmaceutical companies related to VASOSTRICT®, which include the filing of ANDAs for generic versions of VASOSTRICT® and the commencement of bulk compounding of vasopressin, the active ingredient of VASOSTRICT®. These matters are further discussed in Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report under the heading "VASOSTRICT® Related Matters." We have taken and plan to continue to take actions in our best interest to protect our rights with respect to VASOSTRICT®. The introduction of any compounded or generic versions of VASOSTRICT® could result in reductions to our market share, revenues, profitability and cash flows.

Ertapenem for injection, the authorized generic of Invanz®, launched during the third quarter of 2018 and had no sales in 2017 or 2016.

The increase in 2017 in net sales of Other Sterile Injectables was primarily due to the launch of ephedrine sulfate injection and neostigmine methylsulfate injection during the year.

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

The 2017 decrease in U.S. Generic Pharmaceuticals net sales was primarily due to decreases in both price and volume resulting from continued competitive pressure on commoditized generic products and the impact of product rationalization actions resulting from the 2016 and 2017 U.S. Generic Pharmaceuticals segment restructuring initiatives. In addition, combined sales for ezetimibe tablets and quetiapine ER tablets decreased from approximately $292.2 million in 2016 to approximately $250.2 million in 2017 as a result of the loss of marketing exclusivity as discussed above.

International Pharmaceuticals. The decreases in revenue for the International Pharmaceuticals segment in both 2018 and 2017 were primarily attributable to the combined impact of our divestitures of Litha and Somar in the second half of 2017. The decrease in 2018 was partially offset by increases in revenues for certain other products within this segment. For additional detail regarding the divestitures of Litha and Somar refer to Note 3. Discontinued Operations and Divestitures in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Adjusted income from continuing operations before income tax. The following table displays our Adjusted income from continuing operations before income tax by reportable segment for the years ended December 31, 2018, 2017 and 2016 (dollars in thousands):

				% Change	
	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
U.S. Branded - Specialty & Established Pharmaceuticals	$ 368,790	$ 485,515	$ 553,806	(24)%	(12)%
U.S. Branded - Sterile Injectables	695,363	563,103	426,170	23 %	32 %
U.S. Generic Pharmaceuticals	317,892	501,249	653,309	(37)%	(23)%
International Pharmaceuticals	59,094	58,308	84,337	1 %	(31)%
Total segment adjusted income from continuing operations before income tax	$ 1,441,139	$ 1,608,175	$ 1,717,622	(10)%	(6)%

U.S. Branded - Specialty & Established Pharmaceuticals. Amounts were negatively impacted during 2018 as a result of decreased revenues and gross margins related to generic competition and the voluntary cessation of shipments of OPANA® ER by September 1, 2017. Additionally, in 2018, R&D expenses increased as a result of our cellulite treatment development program and legal costs related to certain litigation matters also increased. Our material legal proceedings and other contingent matters are described in more detail in Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

The decrease in 2017 was a result of decreased revenues related to generic competition impacting several products in this segment, the actions taken with respect to OPANA® ER as discussed above and the divestiture of STENDRA® in the third quarter of 2016. These decreases were partially offset by targeted cost reductions in Selling, general and administrative expenses associated with our previously announced restructuring initiatives, as well as the reductions to R&D costs described above.

U.S. Branded - Sterile Injectables. The increases in both 2018 and 2017 were primarily driven by increased revenues and gross margins resulting from strong performance of a variety of products in this segment as described above.

U.S. Generic Pharmaceuticals. The decrease in 2018 was primarily attributable to decreased revenues as described above and the resulting reduction to gross margin. Partially offsetting the decrease were the impacts of reductions to R&D and other operating expenses, including the impact of the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative and the January 2018 Restructuring Initiative, which are described more fully in Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

The decrease in 2017 was primarily attributable to the impact of competitive pressure on commoditized generic products. Partially offsetting the decrease were the impacts of product rationalization actions and other restructuring initiatives, which had the effect of improving gross margin percentage and reducing overall operating expenses in 2017.

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

The table below provides reconciliations of our consolidated Total consolidated loss from continuing operations before income tax, which is determined in accordance with U.S. generally accepted accounting principles (U.S. GAAP), to our total segment adjusted income from continuing operations before income tax for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Total consolidated loss from continuing operations before income tax	$ (938,832)	$ (1,483,004)	$ (3,923,856)
Interest expense, net	521,656	488,228	452,679
Corporate unallocated costs (1)	200,592	165,298	189,043
Amortization of intangible assets	622,339	773,766	876,451
Inventory step-up and certain manufacturing costs that will be eliminated pursuant to integration plans	261	390	125,699
Upfront and milestone payments to partners	45,108	9,483	8,330
Separation benefits and other cost reduction initiatives (2)	86,295	212,448	107,491
Impact of VOLTAREN® Gel generic competition	—	—	(7,750)
Certain litigation-related and other contingencies, net (3)	13,809	185,990	23,950
Asset impairment charges (4)	916,939	1,154,376	3,781,165
Acquisition-related and integration items (5)	21,914	58,086	87,601
Loss on extinguishment of debt	—	51,734	—
Foreign currency impact related to the remeasurement of intercompany debt instruments	(5,486)	(1,403)	366
Other, net (6)	(43,456)	(7,217)	(3,547)
Total segment adjusted income from continuing operations before income tax	$ 1,441,139	$ 1,608,175	$ 1,717,622

(1) Amounts include certain corporate overhead costs, such as headcount, facility and corporate litigation expenses and certain other income and expenses.
(2) Amounts in 2018 primarily relate to employee separation costs of $31.7 million, accelerated depreciation of $35.2 million, charges to increase excess inventory reserves of $2.9 million and other charges of $16.5 million, each of which related primarily to our restructuring initiatives. Amounts in 2017 primarily relate to employee separation costs of $53.0 million, accelerated depreciation of $123.7 million, charges to increase excess inventory reserves of $13.7 million and other charges of $22.0 million. These charges were related primarily to the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative. Amounts in 2016 primarily relate to employee separation costs of $60.2 million, charges to increase excess inventory reserves of $24.5 million and other restructuring costs of $25.1 million, consisting primarily of contract termination fees and building costs. See Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report for discussion of our material restructuring initiatives.
(3) Amounts include adjustments for Litigation-related and other contingencies, net as further described in Note 15. 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 property, plant and equipment as further described in Note 4. Restructuring, Note 7. Fair Value Measurements and Note 9. Property, Plant and Equipment.
(5) Amounts include charges due to changes in the fair value of contingent consideration of $19.9 million, $49.9 million and $23.8 million, respectively. All other amounts are directly related to costs associated with acquisition and integration efforts.
(6) Amounts in 2018 primarily relate to gains on sales of businesses and other assets, as further described in Note 19. Other Income, Net.

LIQUIDITY AND CAPITAL RESOURCES

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

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

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

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

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

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

The obligations of the borrowers under the Credit Agreement are guaranteed by the Company and the subsidiaries of the Company (with certain customary exceptions). The Credit Agreement contains affirmative and negative covenants that the Company 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 Company's affiliates. As of December 31, 2018 and 2017, we were in compliance with all such covenants. In addition, on an annual basis commencing with the year ended December 31, 2018, the Company is required to perform a calculation of Excess Cash Flow (as defined in the Credit Agreement), which could result in certain pre-payments of the principal relating to the Term Loan Facility in accordance with the terms of the Credit Agreement. No such payment is required at December 31, 2018.

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

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

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

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

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

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

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

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

	2018	2017	2016
Net cash flow provided by (used in):			
Operating activities	$ 267,270	$ 553,985	$ 528,143
Investing activities	(17,900)	104,583	(177,552)
Financing activities	(81,572)	(166,993)	(397,186)
Effect of foreign exchange rate	(1,975)	2,515	436
Movement in cash held for sale	—	11,744	(11,744)
Net increase in cash, cash equivalents, restricted cash and restricted cash equivalents	$ 165,823	$ 505,834	$ (57,903)

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

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

The $25.8 million increase in Net cash provided by operating activities in 2017 compared to 2016 was primarily the result of increased cash receipts generated by net sales of ezetimibe tablets and quetiapine ER tablets, which launched in the fourth quarter of 2016 and contributed to a decrease in Accounts receivable in 2017. Cash outlays for mesh settlements decreased $491.1 million during 2017 as compared to 2016. In addition, as a result of continued generic competition on certain legacy branded products and the discontinuation of certain generic products resulting from the 2016 U.S. Generic Pharmaceuticals Restructuring Initiative, cash outlays for customer rebates and chargebacks decreased during 2017 compared to 2016. These increases were partially offset by $760.0 million in U.S. federal income tax refunds received during 2016, compared to $29.8 million received in 2017, increased payments to partners during 2017 resulting from sales of ezetimibe tablets, which launched during the fourth quarter of 2016, and the timing of payments related to certain other current liabilities.

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

The $282.1 million change in cash provided by investing activities in 2017 compared to cash used in investing activities in 2016 relates primarily to an increase in net proceeds from the sales of businesses and other assets of $212.4 million, including the sales of Litha and Somar in the second half of 2017, and a decrease in purchases of property, plant and equipment of $13.2 million. In addition, 2016 activity included acquisitions, net of cash acquired of $30.4 million and payments for product acquisition costs and license fees of $19.2 million, neither of which had comparable activity during 2017.

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

Items contributing to the $230.2 million decrease in cash used in financing activities in 2017 compared to cash used in financing activities in 2016 include an increase in proceeds from issuance of term loans of $3,415.0 million, an increase in proceeds from issuance of notes of $300.0 million and a decrease in payments of revolving debt of $605.0 million, partially offset by an increase in principal payments on term loans of $3,627.3 million, a decrease in amounts of revolving debt drawn of $380.0 million, an increase in payments for deferred financing fees of $57.3 million and an increase in payments for contingent consideration of $29.1 million.

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

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

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

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

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

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

Legal proceedings. We are subject to various patent challenges, product liability claims, government investigations and other legal proceedings in the ordinary course of business. Contingent accruals are recorded when we determine that a loss is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgments regarding future events. For additional discussion of legal proceedings, see Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

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

(1) Includes minimum cash payments related to principal associated with our indebtedness as of December 31, 2018. A discussion of such indebtedness is included above under the caption "Borrowings." The amounts in this table do not reflect any potential early or accelerated principal payments such as the potential payments described in Note 14. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

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

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

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

(6) The amounts included above represent contractual payments for mesh-related product liability settlements and reflect the earliest date that a settlement payment could be due and the largest amount that could be due on that date. These matters are described in more detail in Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

(7) Other obligations and commitments include agreements to purchase third-party assets, products and services and other minimum royalty obligations.

(8) Total generally does not include contractual obligations already included in current liabilities on our Consolidated Balance Sheets, except for current portion of long-term debt, accrued interest, short-term capital lease obligations, mesh-related product liabilities and certain purchase obligations, which are discussed below.

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

Information about our liability for unrecognized tax benefits is included in Note 20. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report under the caption "Uncertain Tax Positions." Due to the nature and timing of the ultimate outcome of these uncertain tax positions, we cannot make a reliable estimate of the amount and period of related future payments. Therefore, our liability has been excluded from the above contractual obligations table.

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

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

Non-U.S. operations. Fluctuations in foreign currency rates resulted in a net gain of $3.8 million in 2018, a net gain of $2.8 million in 2017 and a net loss of $3.0 million in 2016.

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.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

Market risk is the potential loss arising from adverse changes in the financial markets, including interest rates and foreign currency exchange rates.

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our variable-rate indebtedness associated with our Term Loan Facility and Revolving Credit Facility. At both December 31, 2018 and 2017, the aggregate principal amount of such variable-rate indebtedness was $3.4 billion. Borrowings under the Credit Agreement may from time to time bear interest at variable rates, which rates are further described in Note 14. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report, in certain cases subject to a floor. At December 31, 2018 and 2017, a hypothetical 1% increase in the applicable rate over the floor would have resulted in $33.6 million and $34.0 million, respectively, of incremental annual interest expense related to our variable-rate debt borrowings.

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

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

Foreign Currency Exchange Risk

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

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

Fluctuations in foreign currency rates resulted in a net gain of $3.8 million in 2018, a net gain of $2.8 million in 2017 and a net loss of $3.0 million in 2016.

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

Item 8. ***Financial Statements and Supplementary Data***

The information required by this item is contained in the financial statements set forth in Item 15. under the caption "Consolidated Financial Statements" as part of this Annual Report on Form 10-K.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

(a) Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of the Company's Chief Executive Officer and Principal Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as of December 31, 2018. Based on that evaluation, the Company's Chief Executive Officer and Principal Financial Officer concluded that the Company's disclosure controls and procedures were effective as of December 31, 2018.

(b) Management's Report on Internal Control over Financial Reporting

The report of management of the Company regarding internal control over financial reporting is set forth in Item 15. of this Annual Report on Form 10-K under the caption "MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING" and incorporated herein by reference.

(c) Attestation Report of Independent Registered Public Accounting Firm

The attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting is set forth in Item 15. of this Annual Report on Form 10-K under the caption "REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM" and incorporated herein by reference.

(d) Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting during the fiscal quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. ***Other Information***

On February 27, 2019, the Company's subsidiaries, Endo Ventures Limited (EVL) and Par Pharmaceutical, Inc. (PPI), terminated the Membership Interest and Asset Purchase Agreement (Purchase Agreement), dated as of April 26, 2018, with Mendham Holdings, LLC (Seller) and certain other Seller related parties in connection with the acquisition of Somerset Therapeutics, LLC's (Somerset) limited liability company membership interests (LLC Interests) and certain of its assets (the Somerset Assets). In a related transaction, Par Formulations Private Limited (an Indian subsidiary of the Company) also terminated the separate agreements to acquire Wintac Limited's (Wintac) entire business, which operates as Somerset's Indian-based contract developer and manufacturing affiliate, and certain other assets.

The Purchase Agreement gave PPI the right to acquire 100% of the LLC Interests of Somerset and EVL the right to acquire the Somerset Assets for an aggregate cash purchase price of approximately $160 million, subject to customary adjustments for cash, net working capital and indebtedness as described in the Purchase Agreement. The Purchase Agreement also contained certain customary representations, warranties and covenants and provided for indemnification rights of the parties in respect of inaccuracies or breaches of certain representations, warranties and covenants, subject to the limitations set forth in the Purchase Agreement. The closing of the Somerset acquisition was subject to satisfaction of customary closing conditions, including required regulatory approvals and the closing of the acquisition of the Wintac business. Because the regulatory approvals in India for the acquisition of the Wintac business were taking longer than anticipated without clarity as to when those approvals may be received, the Company's subsidiaries exercised their right to terminate the agreements. There are no penalties or other payments associated with the termination of the agreements.

PART III

Item 10. *Directors, Executive Officers and Corporate Governance*

Directors

The information concerning our directors required under this Item is incorporated herein by reference from our proxy statement, which will be filed with the Securities and Exchange Commission, relating to our 2019 Annual General Meeting (2019 Proxy Statement).

Executive Officers

For information concerning Endo's executive officers, see Part 1, Item 1 of this report "Business" under the caption "Executive Officers of the Registrant" and our 2019 Proxy Statement.

Code of Ethics

The information concerning our Code of Conduct is incorporated herein by reference from our 2019 Proxy Statement and can be viewed on our website, the internet address for which is www.endo.com.

Audit Committee

The information concerning our Audit Committee is incorporated herein by reference from our 2019 Proxy Statement.

Audit Committee Financial Experts

The information concerning our Audit Committee Financial Experts is incorporated herein by reference from our 2019 Proxy Statement.

Item 11. *Executive Compensation*

The information required under this Item is incorporated herein by reference from our 2019 Proxy Statement.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

Equity Compensation Plan Information. The following table sets forth aggregate information for the fiscal year ended December 31, 2018 regarding the Company's compensation plans, under which equity securities of Endo may be issued to employees and directors.

	Column A	Column B	Column C
Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights (1)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column A)
Equity compensation plans approved by security holders	19,820,511	$ 20.62	5,487,854
Equity compensation plans not approved by security holders	—	—	—
Total	19,820,511	$ 20.62	5,487,854

(1) Excludes shares of restricted stock units, performance share units and long-term cash incentive awards which will be settled in the Company's ordinary shares.

The other information required under this Item is incorporated herein by reference from our 2019 Proxy Statement.

Item 13. *Certain Relationships and Related Transactions, and Director Independence*

The information required under this Item is incorporated herein by reference from our 2019 Proxy Statement.

Item 14. *Principal Accounting Fees and Services*

Information about the fees for 2018 and 2017 for professional services rendered by our independent registered public accounting firm is incorporated herein by reference from our 2019 Proxy Statement. Our Audit Committee's policy on pre-approval of audit and permissible non-audit services of our independent registered public accounting firm is incorporated by reference from our 2019 Proxy Statement.

The information required under this Item is incorporated herein by reference from our 2019 Proxy Statement.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules***

(a) The following documents are filed as part of this report:

1. *The Consolidated Financial Statements:*

Management's Report on Internal Control Over Financial Reporting
Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of December 31, 2018 and 2017
Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2018, 2017 and 2016
Consolidated Statements of Shareholders' Equity (Deficit) for the years ended December 31, 2018, 2017 and 2016
Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016
Notes to Consolidated Financial Statements

2. *Financial Statement Schedules*

SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS
(in thousands)

	Balance at Beginning of Period	Additions, Costs and Expenses	Deductions, Write-offs	Other (1)	Balance at End of Period
Valuation Allowance For Deferred Tax Assets:					
Year Ended December 31, 2016	$ 426,991	$ 4,416,478	$ (2,039)	$ (221)	$ 4,841,209
Year Ended December 31, 2017	$ 4,841,209	$ 3,811,982	$ —	$ (590,216)	$ 8,062,975
Year Ended December 31, 2018	$ 8,062,975	$ 2,569,175	$ (2,259)	$ (752,274)	$ 9,877,617

(1) Represents the remeasurement of net deferred tax assets due to changes in statutory tax rates.

All other financial statement schedules have been omitted because they are not applicable or the required information is included in the Consolidated Financial Statements or notes thereto.

3. *Exhibits:*

		Incorporated by Reference from:		
Number	**Description**	**File Number**	**Filing Type**	**Filing Date**
2.1†	Purchase Agreement, dated March 2, 2015, by and among American Medical Systems Holdings, Inc., Endo Health Solutions Inc., and Boston Scientific Corporation	001-36326	Quarterly Report on Form 10-Q	May 11, 2015
2.2†	Agreement and Plan of Merger, dated as of May 18, 2015, by and among Par Pharmaceutical Holdings, Inc., a Delaware corporation, Endo International plc, a public limited company incorporated under the laws of Ireland, Endo Limited, a private limited company incorporated under the laws of Ireland, Endo Health Solutions Inc., a Delaware corporation, Banyuls Limited, a private limited company incorporated under the laws of Ireland, Hawk Acquisition ULC, a Bermudian unlimited liability company and Shareholder Representative Services LLC, a Colorado limited liability company, solely as the Stakeholder Representative (as defined therein)	001-36326	Current Report on Form 8-K	May 21, 2015
2.3*†	Sale Agreement, dated as of February 27, 2017, by and among Acino Pharma AG and the Endo Luxembourg Finance Company I S.à.r.l., Endo Luxembourg Finance Company II S.à.r.l. and Endo Ventures Limited	001-36326	Quarterly Report on Form 10-Q	May 9, 2017
2.4	Purchase Agreement, dated as of June 30, 2017, by and among Endo Somar Holdings B.V., Endo Luxembourg Finance Company I S.à r.l., Endo Global Finance LLC, Endo Luxembourg Finance Company II S.à r.l. and AI Global Investments (Netherlands) PCC Limited, acting for and on behalf of the Soar Cell	001-36326	Quarterly Report on Form 10-Q	August 8, 2017

		Incorporated by Reference from:		
Number	Description	File Number	Filing Type	Filing Date
3.1	Certificate of Incorporation on re-registration as a public limited company of Endo International plc	001-36326	Current Report on Form 8-K12B	February 28, 2014
3.2	Memorandum and Articles of Association of Endo International plc, dated as of October 31, 2013 and as amended as of June 8, 2017	001-36326	Quarterly Report on Form 10-Q	August 8, 2017
4.1	Specimen Share Certificate of Endo International plc	333-194253	Form S-8	February 28, 2014
4.2	Indenture among Endo Health Solutions Inc. (formerly, Endo Pharmaceuticals Holdings Inc.), the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (including Form of 7 1/4% Senior Notes due 2022 and Form of Supplemental Indenture relating to the 7 1/4% Senior Notes due 2022)	001-15989	Current Report on Form 8-K	June 9, 2011
4.3	Fourth Supplemental Indenture, among Generics Bidco II, LLC, Generics International (US Holdco), Inc., Generics International (US Midco), Inc., Generics International (US Parent), Inc., Moores Mill Properties L.L.C., Quartz Specialty Pharmaceuticals, LLC and Wood Park Properties LLC, as guaranteeing subsidiaries, Endo Health Solutions Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated September 26, 2011, to the Indenture among Endo Health Solutions Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011, governing Endo Health Solutions Inc.'s 7 1/4% Senior Notes due 2022	001-15989	Annual Report on Form 10-K	March 3, 2014
4.4	Fifth Supplemental Indenture, among Endo Health Solutions Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated as of April 17, 2014, to the Indenture among Endo Health Solutions Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated as of June 8, 2011, governing Endo Health Solutions Inc.'s 7 1/4% Senior Notes due 2022	001-36326	Current Report on Form 8-K	April 17, 2014
4.5	Indenture, dated December 19, 2013, between Endo Finance LLC (formerly, Endo Finance Co.) and Wells Fargo Bank, National Association, as trustee (including Form of 5.75% Senior Notes due 2022 and Form of Supplemental Indenture relating to the 5.75% Senior Notes due 2022)	001-15989	Current Report on Form 8-K	December 19, 2013
4.6	Supplemental Indenture, dated February 28, 2014, among Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, to the Indenture, dated December 19, 2013	001-36326	Current Report on Form 8-K12B	February 28, 2014
4.7	Supplemental Indenture, dated March 27, 2015, among Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, to the Indenture, dated December 19, 2013	001-36326	Annual Report on Form 10-K	February 29, 2016
4.8	Indenture, dated May 6, 2014, among Endo Finance LLC, Endo Finco Inc. the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 7.25% Senior Notes due 2022 (including Form of 7.25% Senior Notes due 2022 and Form of Supplemental Indenture relating to the 7.25% Senior Notes due 2022)	001-36326	Current Report on Form 8-K	May 7, 2014
4.9	Supplemental Indenture, dated March 27, 2015, among Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, to the Indenture, dated May 6, 2014	001-36326	Annual Report on Form 10-K	February 29, 2016
4.10	Registration Rights Agreement, dated May 6, 2014, by and among Endo Finance LLC, Endo Finco Inc. the guarantors named therein and RBC Capital Markets, LLC and Deutsche Bank Securities Inc., relating to the 7.25% Senior Notes due 2022 (including Form of Counterpart to the Registration Rights Agreement relating to the 7.25% Senior Notes due 2022)	001-36326	Current Report on Form 8-K	May 7, 2014

		Incorporated by Reference from:		
Number	Description	File Number	Filing Type	Filing Date
4.11	Indenture, dated June 30, 2014, among Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 5.375% Senior Notes due 2023 (including Form of 5.375% Senior Notes due 2023 and Form of Supplemental Indenture relating to the 5.375% Senior Notes due 2023)	001-36326	Current Report on Form 8-K	July 1, 2014
4.12	Supplemental Indenture, dated March 27, 2015, among Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, to the Indenture, dated June 30, 2014	001-36326	Annual Report on Form 10-K	February 29, 2016
4.13	Registration Rights Agreement, dated June 30, 2014, by and among Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Citigroup Global Markets Inc. and RBC Capital Markets, LLC, relating to the 5.375% Senior Notes due 2023 (including Form of Counterpart to the Registration Rights Agreement relating to the 5.375% Senior Notes due 2023)	001-36326	Current Report on Form 8-K	July 1, 2014
4.14	Indenture, dated January 27, 2015, among Endo Designated Activity Company (formerly, Endo Limited), Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 6.00% Senior Notes due 2025 (including Form of 6.00% Senior Notes due 2025 and Form of Supplemental Indenture relating to the 6.00% Senior Notes due 2025)	001-36326	Current Report on Form 8-K	January 27, 2015
4.15	Supplemental Indenture, dated March 27, 2015, among Endo Designated Activity Company (formerly, Endo Limited), Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, to the Indenture, dated January 27, 2015	001-36326	Annual Report on Form 10-K	February 29, 2016
4.16	Registration Rights Agreement, dated January 27, 2015, by and among Endo Designated Activity Company (formerly, Endo Limited), Endo Finance LLC, Endo Finco Inc., the guarantors named therein and RBC Capital Markets, LLC and Citigroup Global Markets Inc., relating to the 6.00% Senior Notes due 2025 (including Form of Counterpart to the Registration Rights Agreement relating to the 6.00% Senior Notes due 2025)	001-36326	Current Report on Form 8-K	January 27, 2015
4.17	Indenture, dated July 9, 2015, among Endo Designated Activity Company (formerly, Endo Limited), Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 6.000% Senior Notes due 2023 (including Form of 6.000% Notes due 2023 and Form of Supplemental Indenture relating to the 6.000% Notes due 2023)	001-36326	Current Report on Form 8-K	July 9, 2015
4.18	Indenture, dated as of April 27, 2017, among Endo Designated Activity Company, Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 5.875% Senior Secured Notes due 2024 (including Form of 5.875% Senior Secured Notes due 2024 and Form of Supplemental Indenture relating to the 5.875% Senior Secured Notes due 2024)	001-36326	Current Report on Form 8-K	April 28, 2017
4.19	Shareholders Agreement, dated as of May 18, 2015, by and among Endo International plc and the signatories thereto	001-36326	Current Report on Form 8-K	May 21, 2015
4.19.1	Amendment No. 1 to Shareholders and Registration Rights Agreements, dated as of May 5, 2016, by and among Endo International plc and the signatories thereto	001-36326	Current Report on Form 8-K	May 5, 2016
4.20	Registration Rights Agreement dated April 26, 2013, by and between Auxilium Pharmaceuticals, Inc., a Delaware corporation and GTCR Fund IX/A, L.P., a Delaware limited partnership, solely in its capacity as representative for the GTCR Fund IX/B, L.P., and the Actient Holdings LLC's Unitholders and Optionholders	000-50855	Current Report on Form 8-K	April 29, 2013
4.21	Registration Rights Agreement, dated as of May 18, 2015, by and among Endo International plc and the persons listed on Schedule A thereto	001-36326	Current Report on Form 8-K	May 21, 2015

		Incorporated by Reference from:		
Number	Description	File Number	Filing Type	Filing Date
10.1	Amended and Restated Executive Deferred Compensation Plan	001-36326	Quarterly Report on Form 10-Q	August 8, 2018
10.2	Amended and Restated 401(k) Restoration Plan	001-15989	Annual Report on Form 10-K	March 1, 2013
10.3	Directors Deferred Compensation Plan	001-15989	Annual Report on Form 10-K	March 1, 2013
10.4	Endo International plc Amended and Restated Employee Stock Purchase Plan	333-194253	Form S-8	February 28, 2014
10.5	Credit Agreement, dated as of April 27, 2017, among Endo International, plc, as parent, 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	001-36326	Current Report on Form 8-K	April 28, 2017
10.6*	Second Amended and Restated Development and License Agreement, dated August 31, 2011, by and between BioSpecifics Technologies Corp. and Auxilium	000-50855	Current Report on Form 8-K	September 1, 2011
10.6.1*	First Amendment to Second Amended and Restated Development and License Agreement, dated February 1, 2016, by and between BioSpecifics Technologies Corp. and Endo Global Ventures	001-36326	Annual Report on Form 10-K	February 29, 2016
10.7*	Supply Agreement, dated June 26, 2008, between Auxilium and Hollister-Stier Laboratories LLC	000-50855	Quarterly Report on Form 10-Q	August 8, 2008
10.8	Endo International plc Amended and Restated 2015 Stock Incentive Plan	001-36326	Current Report on Form 8-K	June 7, 2018
10.9	Form of Stock Option Agreement under the Endo International plc Amended and Restated 2015 Stock Incentive Plan	001-36326	Quarterly Report on Form 10-Q	November 8, 2018
10.10	Form of Stock Award Agreement under the Endo International plc Amended and Restated 2015 Stock Incentive Plan	001-36326	Quarterly Report on Form 10-Q	November 8, 2018
10.11	Form of Performance Award Agreement under the Endo International plc Amended and Restated 2015 Stock Incentive Plan	001-36326	Quarterly Report on Form 10-Q	November 8, 2018
10.12	Form of Long-Term Cash Incentive Award Agreement under the Amended and Restated 2015 Stock Incentive Plan	001-36326	Quarterly Report on Form 10-Q	August 8, 2018
10.13	Form of Indemnification Agreement with Endo Health Solutions Inc.	001-36326	Annual Report on Form 10-K	February 29, 2016
10.14	Director Confidentiality Agreement, dated as of May 5, 2016, by and among Endo International plc, Todd B. Sisitsky and TPG Global, LLC	001-36326	Current Report on Form 8-K	May 5, 2016
10.15	Form of Indemnification Agreement with Endo International plc	001-36326	Quarterly Report on Form 10-Q	May 6, 2016
10.16*	Master Supply Agreement, dated as of April 22, 2016, by and between Endo Ventures Limited and Jubilant HollisterStier LLC	001-36326	Quarterly Report on Form 10-Q	August 9, 2016
10.17	Executive Employment Agreement between Endo Health Solutions Inc. and Paul Campanelli, dated as of September 23, 2016	001-36326	Current Report on Form 8-K	September 29, 2016
10.18	Executive Employment Agreement between Endo Health Solutions Inc. and Terrance J. Coughlin, dated December 9, 2016	001-36326	Current Report on Form 8-K/A	December 9, 2016
10.19	Executive Employment Agreement between Endo Health Solutions Inc. and Blaise Coleman, dated December 22, 2016	001-36326	Current Report on Form 8-K/A	December 22, 2016
10.20	Executive Employment Agreement between Endo Health Solutions Inc. and Matthew J. Maletta, dated as of February 13, 2018	001-36326	Current Report on Form 8-K	February 15, 2018
10.21	Executive Employment Agreement between Endo Health Solutions Inc. and Antonio Pera, dated as of December 5, 2016	Not applicable; filed herewith		
14.1	Our Code of Conduct	Not applicable; filed herewith		
21.1	Subsidiaries of the Registrant	Not applicable; filed herewith		

Number	Description	Incorporated by Reference from: File Number	Filing Type	Filing Date
23.1	Consent of PricewaterhouseCoopers LLP	Not applicable; filed herewith		
24.1	Power of Attorney	Not applicable; filed herewith		
31.1	Certification of the President and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Not applicable; filed herewith		
31.2	Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Not applicable; filed herewith		
32.1	Certification of the President and Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Not applicable; furnished herewith		
32.2	Certification of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Not applicable; furnished herewith		
101	The following materials from Endo International plc's Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Consolidated Statements of Shareholders' Equity (Deficit), (v) the Consolidated Statements of Cash Flows and (vi) the Notes to Consolidated Financial Statements	Not applicable; submitted herewith		

* Confidential portions of this exhibit (indicated by asterisks) have been redacted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

† Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished supplementally to the Securities and Exchange Commission upon request; provided, however that Endo International plc may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedules or exhibits so furnished.

Item 16. ***Form 10-K Summary***

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ENDO INTERNATIONAL PLC

(Registrant)

/s/ PAUL V. CAMPANELLI

Name: **Paul V. Campanelli**

Title: **President and Chief Executive Officer**

(Principal Executive Officer)

Date: February 28, 2019

Pursuant to the requirements of the Securities Exchange of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ PAUL V. CAMPANELLI Paul V. Campanelli	Director, President and Chief Executive Officer (Principal Executive Officer)	February 28, 2019
/S/ BLAISE COLEMAN Blaise Coleman	Executive Vice President, Chief Financial Officer (Principal Financial Officer)	February 28, 2019
/S/ CARRIE A. NICHOL Carrie A. Nichol	Senior Vice President, Controller, Chief Accounting Officer (Principal Accounting Officer)	February 28, 2019
* Roger H. Kimmel	Chairman and Director	February 28, 2019
* Shane M. Cooke	Director	February 28, 2019
* Nancy J. Hutson, Ph.D.	Director	February 28, 2019
* Michael Hyatt	Director	February 28, 2019
* Sharad S. Mansukani, M.D.	Director	February 28, 2019
* William P. Montague	Director	February 28, 2019
* Todd B. Sisitsky	Director	February 28, 2019
*By: /S/ MATTHEW J. MALETTA Matthew J. Maletta	Attorney-in-fact pursuant to a Power of Attorney filed with this Report as Exhibit 24	February 28, 2019

INDEX TO FINANCIAL STATEMENTS

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Endo International plc is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Endo International plc's internal control over financial reporting was designed to provide reasonable assurance regarding the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Endo International plc's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2018. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework (2013)*. Based on our assessment we determined that, as of December 31, 2018, the Company's internal control over financial reporting is effective based on those criteria.

Endo International plc's independent registered public accounting firm has issued its report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2018. This report appears on page F-3.

/S/ PAUL V. CAMPANELLI

Paul V. Campanelli

Director, President and Chief Executive Officer
(Principal Executive Officer)

/S/ BLAISE COLEMAN

Blaise Coleman

Executive Vice President, Chief Financial Officer
(Principal Financial Officer)

February 28, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Endo International plc:

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Endo International plc and its subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, shareholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2018, including the related notes and schedule of valuation and qualifying accounts for each of the three years in the period ended December 31, 2018 appearing under Item 15(a)(2) (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania
February 28, 2019

We have served as the Company's auditor since 2014.

ENDO INTERNATIONAL PLC
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2018 AND 2017
(In thousands, except share and per share data)

	December 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,149,113	$ 986,605
Restricted cash and cash equivalents	305,368	320,453
Accounts receivable, net	470,570	517,436
Inventories, net	322,179	391,437
Prepaid expenses and other current assets	56,139	43,098
Income taxes receivable	39,781	12,048
Total current assets	$ 2,343,150	$ 2,271,077
MARKETABLE SECURITIES	738	1,456
PROPERTY, PLANT AND EQUIPMENT, NET	498,892	523,971
GOODWILL	3,764,636	4,450,082
OTHER INTANGIBLES, NET	3,457,306	4,317,684
DEFERRED INCOME TAXES	678	11,582
OTHER ASSETS	66,993	59,728
TOTAL ASSETS	$ 10,132,393	$ 11,635,580
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 1,009,200	$ 1,096,825
Current portion of legal settlement accrual	905,085	1,087,793
Current portion of long-term debt	34,150	34,205
Income taxes payable	1,661	2,086
Total current liabilities	$ 1,950,096	$ 2,220,909
DEFERRED INCOME TAXES	34,487	43,131
LONG-TERM DEBT, LESS CURRENT PORTION, NET	8,224,269	8,242,032
LONG-TERM LEGAL SETTLEMENT ACCRUAL, LESS CURRENT PORTION	—	210,450
OTHER LIABILITIES	421,824	434,178
COMMITMENTS AND CONTINGENCIES (NOTE 15)		
SHAREHOLDERS' (DEFICIT) EQUITY:		
Euro deferred shares, $0.01 par value; 4,000,000 shares authorized and issued at both December 31, 2018 and December 31, 2017	46	48
Ordinary shares, $0.0001 par value; 1,000,000,000 shares authorized; 224,382,791 and 223,331,706 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	22	22
Additional paid-in capital	8,855,810	8,791,170
Accumulated deficit	(9,124,932)	(8,096,539)
Accumulated other comprehensive loss	(229,229)	(209,821)
Total shareholders' (deficit) equity	$ (498,283)	$ 484,880
TOTAL LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY	$ 10,132,393	$ 11,635,580

See Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016
(In thousands, except per share data)

	2018	2017	2016
TOTAL REVENUES	$ 2,947,078	$ 3,468,858	$ 4,010,274
COSTS AND EXPENSES:			
Cost of revenues	1,631,682	2,228,530	2,634,973
Selling, general and administrative	646,037	629,874	770,728
Research and development	185,826	172,067	183,372
Litigation-related and other contingencies, net	13,809	185,990	23,950
Asset impairment charges	916,939	1,154,376	3,781,165
Acquisition-related and integration items	21,914	58,086	87,601
OPERATING LOSS FROM CONTINUING OPERATIONS	$ (469,129)	$ (960,065)	$ (3,471,515)
INTEREST EXPENSE, NET	521,656	488,228	452,679
LOSS ON EXTINGUISHMENT OF DEBT	—	51,734	—
OTHER INCOME, NET	(51,953)	(17,023)	(338)
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAX	$ (938,832)	$ (1,483,004)	$ (3,923,856)
INCOME TAX EXPENSE (BENEFIT)	22,935	(250,293)	(700,084)
LOSS FROM CONTINUING OPERATIONS	$ (961,767)	$ (1,232,711)	$ (3,223,772)
DISCONTINUED OPERATIONS, NET OF TAX (NOTE 3)	(69,702)	(802,722)	(123,278)
CONSOLIDATED NET LOSS	$ (1,031,469)	$ (2,035,433)	$ (3,347,050)
Less: Net income attributable to noncontrolling interests	—	—	16
NET LOSS ATTRIBUTABLE TO ENDO INTERNATIONAL PLC	$ (1,031,469)	$ (2,035,433)	$ (3,347,066)
NET LOSS PER SHARE ATTRIBUTABLE TO ENDO INTERNATIONAL PLC ORDINARY SHAREHOLDERS—BASIC:			
Continuing operations	$ (4.29)	$ (5.52)	$ (14.48)
Discontinued operations	(0.32)	(3.60)	(0.55)
Basic	$ (4.61)	$ (9.12)	$ (15.03)
NET LOSS PER SHARE ATTRIBUTABLE TO ENDO INTERNATIONAL PLC ORDINARY SHAREHOLDERS—DILUTED:			
Continuing operations	$ (4.29)	$ (5.52)	$ (14.48)
Discontinued operations	(0.32)	(3.60)	(0.55)
Diluted	$ (4.61)	$ (9.12)	$ (15.03)
WEIGHTED AVERAGE SHARES:			
Basic	223,960	223,198	222,651
Diluted	223,960	223,198	222,651

See Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016
(In thousands)

	2018		2017		2016	
CONSOLIDATED NET LOSS		$ (1,031,469)		$ (2,035,433)		$ (3,347,050)
OTHER COMPREHENSIVE (LOSS) INCOME:						
Net unrealized gain (loss) on securities, net of tax:						
Unrealized gain (loss) arising during the period	$ —		$ (515)		$ (914)	
Less: reclassification adjustments for (gain) loss realized in net loss	—	—	—	(515)	(6)	(920)
Net unrealized (loss) gain on foreign currency, net of tax:						
Foreign currency translation (loss) gain arising during the period	$ (19,408)		$ 31,202		$ 31,729	
Less: reclassification adjustments for loss realized in net loss	—	(19,408)	112,926	144,128	—	31,729
OTHER COMPREHENSIVE (LOSS) INCOME		$ (19,408)		$ 143,613		$ 30,809
CONSOLIDATED COMPREHENSIVE LOSS		$ (1,050,877)		$ (1,891,820)		$ (3,316,241)
Less: Net income attributable to noncontrolling interests		—		—		16
Less: Other comprehensive income attributable to noncontrolling interests		—		—		38
COMPREHENSIVE LOSS ATTRIBUTABLE TO ENDO INTERNATIONAL PLC		$ (1,050,877)		$ (1,891,820)		$ (3,316,295)

See Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016
(In thousands, except share data)

	Endo International plc Shareholders									
	Ordinary Shares		Euro Deferred Shares							
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Endo International plc Shareholders' Equity (Deficit)	Noncontrolling Interests	Total Shareholders' Equity (Deficit)
BALANCE, JANUARY 1, 2016	222,124,282	$ 22	4,000,000	$ 43	$ 8,693,385	$(2,341,215)	$ (384,205)	$ 5,968,030	$ (54)	$ 5,967,976
Net (loss) income	—	—	—	—	—	(3,347,066)	—	(3,347,066)	16	(3,347,050)
Other comprehensive income	—	—	—	—	—	—	30,771	30,771	38	30,809
Compensation related to share-based awards	—	—	—	—	59,769	—	—	59,769	—	59,769
Exercise of options	62,589	—	—	—	1,952	—	—	1,952	—	1,952
Tax benefits of share awards, net	—	—	—	—	(5,449)	—	—	(5,449)	—	(5,449)
Issuance of ordinary shares related to the employee stock purchase plan	306,918	—	—	—	5,119	—	—	5,119	—	5,119
Ordinary shares issued	460,386	—	—	—	—	—	—	—	—	—
Tax withholding for restricted shares	—	—	—	—	(11,500)	—	—	(11,500)	—	(11,500)
Other	—	—	—	(1)	(36)	—	—	(37)	—	(37)
BALANCE, DECEMBER 31, 2016, prior to the adoption of ASU 2016-16	222,954,175	$ 22	4,000,000	$ 42	$ 8,743,240	$(5,688,281)	$ (353,434)	$ 2,701,589	$ —	$ 2,701,589
Effect of adopting ASU 2016-16 (NOTE 17)	—	—	—	—	—	(372,825)	—	(372,825)	—	(372,825)
BALANCE, JANUARY 1, 2017	222,954,175	$ 22	4,000,000	$ 42	$ 8,743,240	$(6,061,106)	$ (353,434)	$ 2,328,764	$ —	$ 2,328,764
Net loss	—	—	—	—	—	(2,035,433)	—	(2,035,433)	—	(2,035,433)
Other comprehensive income	—	—	—	—	—	—	143,613	143,613	—	143,613
Compensation related to share-based awards	—	—	—	—	50,149	—	—	50,149	—	50,149
Ordinary shares issued	377,531	—	—	—	—	—	—	—	—	—
Tax withholding for restricted shares	—	—	—	—	(2,078)	—	—	(2,078)	—	(2,078)
Other	—	—	—	6	(141)	—	—	(135)	—	(135)
BALANCE, DECEMBER 31, 2017, prior to the adoption of ASC 606	223,331,706	$ 22	4,000,000	$ 48	$ 8,791,170	$(8,096,539)	$ (209,821)	$ 484,880	$ —	$ 484,880
Effect of adopting ASC 606 (NOTE 17)	—	—	—	—	—	3,076	—	3,076	—	3,076
BALANCE, JANUARY 1, 2018	223,331,706	$ 22	4,000,000	$ 48	$ 8,791,170	$(8,093,463)	$ (209,821)	$ 487,956	$ —	$ 487,956
Net loss	—	—	—	—	—	(1,031,469)	—	(1,031,469)	—	(1,031,469)
Other comprehensive loss	—	—	—	—	—	—	(19,408)	(19,408)	—	(19,408)
Compensation related to share-based awards	—	—	—	—	54,071	—	—	54,071	—	54,071
Exercise of options	94,392	—	—	—	933	—	—	933	—	933
Ordinary shares issued	956,693	—	—	—	—	—	—	—	—	—
LTCI modification (NOTE 18)	—	—	—	—	14,936	—	—	14,936	—	14,936
Tax withholding for restricted shares	—	—	—	—	(5,375)	—	—	(5,375)	—	(5,375)
Other	—	—	—	(2)	75	—	—	73	—	73
BALANCE, DECEMBER 31, 2018	224,382,791	$ 22	4,000,000	$ 46	$ 8,855,810	$(9,124,932)	$ (229,229)	$ (498,283)	$ —	$ (498,283)

See Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016
(In thousands)

	2018	2017	2016
OPERATING ACTIVITIES:			
Consolidated net loss	$ (1,031,469)	$ (2,035,433)	$ (3,347,050)
Adjustments to reconcile Consolidated net loss to Net cash provided by operating activities:			
Depreciation and amortization	723,707	983,765	983,309
Inventory step-up	261	390	108,768
Share-based compensation	54,071	50,149	59,769
Amortization of debt issuance costs and discount	20,514	22,694	28,514
Deferred income taxes	5,557	(156,129)	(745,341)
Change in fair value of contingent consideration	19,910	49,949	23,823
Loss on extinguishment of debt	—	51,734	—
Asset impairment charges	916,939	1,154,376	3,802,493
(Gain) loss on sale of business and other assets	(45,155)	(13,809)	3,192
Changes in assets and liabilities which provided (used) cash:			
Accounts receivable	17,090	484,710	(502)
Inventories	67,269	147,189	66,876
Prepaid and other assets	(12,797)	5,345	69,273
Accounts payable, accrued expenses and other liabilities	(425,336)	(87,944)	(1,207,047)
Income taxes payable/receivable	(43,291)	(103,001)	682,066
Net cash provided by operating activities	$ 267,270	$ 553,985	$ 528,143
INVESTING ACTIVITIES:			
Purchases of property, plant and equipment, excluding capitalized interest	(83,398)	(125,654)	(138,856)
Capitalized interest payments	(3,549)	—	—
Acquisitions, net of cash and restricted cash acquired	—	—	(30,394)
Decrease in notes receivable	—	7,000	—
Product acquisition costs and license fees	(3,000)	—	(19,206)
Proceeds from sale of business and other assets, net	70,369	223,237	10,870
Other investing activities	1,678	—	34
Net cash (used in) provided by investing activities	$ (17,900)	$ 104,583	$ (177,552)

	2018	2017	2016
FINANCING ACTIVITIES:			
Proceeds from issuance of notes	—	300,000	—
Proceeds from issuance of term loans	—	3,415,000	—
Principal payments on term loans	(34,150)	(3,730,951)	(103,625)
Proceeds from draw of revolving debt	—	—	380,000
Repayments of revolving debt	—	—	(605,000)
Principal payments on other indebtedness	(5,222)	(6,154)	(7,736)
Deferred financing fees	—	(57,773)	(500)
Payments for contingent consideration	(37,758)	(85,037)	(55,896)
Payments of tax withholding for restricted shares	(5,375)	(2,078)	(11,500)
Exercise of options	933	—	1,952
Issuance of ordinary shares related to the employee stock purchase plan	—	—	5,119
Net cash used in financing activities	$ (81,572)	$ (166,993)	$ (397,186)
Effect of foreign exchange rate	(1,975)	2,515	436
Movement in cash held for sale	—	11,744	(11,744)
NET INCREASE IN CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS	$ 165,823	$ 505,834	$ (57,903)
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, BEGINNING OF PERIOD	1,311,014	805,180	863,083
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, END OF PERIOD	$ 1,476,837	$ 1,311,014	$ 805,180
SUPPLEMENTAL INFORMATION:			
Cash paid for interest, excluding capitalized interest	$ 515,042	$ 467,017	$ 429,172
Cash paid for income taxes	$ 17,639	$ 28,675	$ 63,983
Cash received from U.S. Federal tax refunds	$ —	$ 29,825	$ 759,950
Cash paid into Qualified Settlement Funds for mesh legal settlements	$ 336,648	$ 668,306	$ 831,131
Cash paid out of Qualified Settlement Funds for mesh legal settlements	$ 353,032	$ 632,176	$ 1,134,734
Other cash distributions for mesh legal settlements	$ 25,222	$ 19,243	$ 7,830

See Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016

NOTE 1. DESCRIPTION OF BUSINESS

Endo International plc is an Ireland-domiciled, global specialty pharmaceutical company focused on generic and branded pharmaceuticals. We aim to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of generic and branded drugs to meet patients' needs. Unless otherwise indicated or required by the context, references throughout to "Endo," the "Company," "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. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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 revenue recognition, including sales deductions, financial instruments, long-lived assets, goodwill, other intangibles, income taxes, contingencies and share-based compensation, among others. Some of these estimates can be subjective and complex. Although we believe that our estimates and assumptions are reasonable, there may be other reasonable estimates or assumptions that differ significantly from ours. Further, our estimates and assumptions are based upon information available at the time they were made. Actual results may differ significantly from our estimates.

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

Customer, Product and Supplier Concentration. We primarily sell our generic and branded pharmaceuticals to wholesalers, retail drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, hospitals and government agencies. Our wholesalers and distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies and managed health care organizations. Customers in the managed health care market include health maintenance organizations, nursing homes, hospitals, clinics, pharmacy benefit management companies and mail order customers. Total revenues from direct customers that accounted for 10% or more of our total consolidated revenues during the years ended December 31, 2018, 2017 and 2016 are as follows:

	2018	2017	2016
AmerisourceBergen Corporation	32%	25%	25%
McKesson Corporation	27%	25%	27%
Cardinal Health, Inc.	26%	25%	26%

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

VASOSTRICT® accounted for 15% and 12% of our 2018 and 2017 total revenues, respectively. No other products accounted for 10% or more of our total revenues during the years ended December 31, 2018, 2017 or 2016.

We have agreements with certain third parties for the manufacture, supply and processing of certain of our existing pharmaceutical products. See Note 15. Commitments and Contingencies for information on material manufacturing, supply and other service agreements.

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

Revenue Recognition and Sales Deductions. The Company adopted *Accounting Standards Codification Topic 606, Revenue from Contracts with Customers* (ASC 606) on January 1, 2018 using the modified retrospective method for all revenue-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 revenue 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 revenue 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 revenue consists almost entirely of sales of our pharmaceutical products to customers, whereby we ship products to a customer pursuant to a purchase order. For contracts such as these, revenue 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 revenue 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 Company 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 revenue reversal will not occur when the uncertainty associated with the variable consideration is resolved. Payment terms for these types of contracts generally fall within 30 to 90 days of invoicing.

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

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

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

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

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

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

We participate in various federal and state government-managed programs whereby discounts and rebates are provided to participating government entities. For example, Medicaid rebates are amounts owed based upon contractual agreements or legal requirements with public sector (Medicaid) benefit providers after the final dispensing of the product by a pharmacy to a benefit plan participant.

Chargebacks—We market and sell products to both: (i) direct customers including wholesalers, distributors, warehousing pharmacy chains and other direct purchasing groups and (ii) indirect customers including independent pharmacies, non-warehousing chains, managed-care organizations, group purchasing organizations and government entities. We enter into agreements with certain of our indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price. Such credit is called a chargeback.

Contract Assets and Contract Liabilities. Contract assets represent the Company's right to consideration in exchange for goods or services that the Company has transferred to a customer when that right is conditioned on something other than the passage of time including, for example, the entity's future performance. The Company records revenue 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 Company's right to consideration becomes unconditional, the contract asset amount is reclassified as Accounts receivable.

Contract liabilities represent the Company's obligation to transfer goods or services to a customer. The Company 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 revenue 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.

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

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

Restricted Cash and Cash Equivalents. Cash and cash equivalents that are restricted as to withdrawal or use under the terms of certain contractual agreements are excluded from Cash and cash equivalents in the Consolidated Balance Sheets. For additional information see Note 7. Fair Value Measurements.

Marketable Securities. The Company has equity securities, which consist of investments in the stock of publicly traded companies. For additional information see Note 7. Fair Value Measurements.

Accounts Receivable. Accounts receivable are stated at their net realizable value and the Company maintains an allowance for doubtful accounts against gross accounts receivable. The allowance is not material to the Company's Consolidated Financial Statements at December 31, 2018 and 2017. In addition, accounts receivable 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 Company to significant concentrations of credit risk consist primarily of cash equivalents, restricted cash equivalents, marketable debt securities and accounts receivable. From time to time, we invest our excess cash in high-quality, liquid money market instruments and time deposits maintained by major banks and financial institutions. We have not experienced any losses on our cash equivalents.

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

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

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

Property, Plant and Equipment. Property, plant and equipment 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 property plant and equipment are capitalized as assets under construction. Once an asset has been put into service, depreciation expense is taken over the estimated useful life of the related assets or, in the case of leasehold improvements and capital lease assets, over the shorter of the estimated useful life or the lease term. Depreciation expense is recorded on a straight-line basis. Depreciation expense is not recorded on Assets held for sale. Gains and losses on disposals are included in Other income, net in the Consolidated Statements of Operations. Depreciation is based on the following estimated useful lives, as of December 31, 2018:

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

Computer Software. The Company 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 Property, plant and equipment, net in the Consolidated Balance Sheets and depreciated beginning when the software project is substantially complete and the asset is ready for its intended use. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

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

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

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

Finite-Lived Intangible Assets. Our finite-lived intangible assets, which consist of license rights and developed technology, are initially recorded at fair value upon acquisition. There are several methods that can be used to determine fair value. For intangible assets, we typically use the income method. This method starts with our forecast of all of the expected future net cash flows. Revenues are 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 risk factors associated with the cash flow streams.

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

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

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

Long-Lived Asset Impairment Testing. Long-lived assets, including property, plant and equipment 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 Statements of Operations in the period that the impairment occurs.

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

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

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

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

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

Share Repurchases. The Company 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 Company records the difference between the weighted average cost of such ordinary shares and the par value of the ordinary shares as an adjustment to Accumulated deficit in the Consolidated Balance Sheets.

Advertising Costs. Advertising costs are expensed as incurred and included in Selling, general and administrative expenses in the Consolidated Statements of Operations. Advertising costs amounted to $49.6 million, $42.0 million and $47.9 million for the years ended December 31, 2018, 2017 and 2016, respectively.

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

Share-Based Compensation. The Company 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 Company 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 18. 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 Company operates in various jurisdictions both inside and outside of the U.S. While the Company's reporting currency is the U.S. dollar (USD), the Company has concluded that certain of its distinct and separable operations have functional currencies other than the USD. Further, certain of the Company's operations hold assets and liabilities and recognize income and expenses denominated in various local currencies, which may differ from their functional currencies.

Assets and liabilities are first remeasured from local currency to functional currency, generally using end-of-period exchange rates. Foreign currency income and expenses are generally remeasured using average exchange rates in effect during the year. In the case of nonmonetary assets and liabilities such as inventories, prepaid expenses, property, plant and equipment, 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 income, net in the Consolidated Statements of Operations.

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

Income Taxes. The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. The Company 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 Company considers all available positive and negative evidence, including projected future taxable income, tax-planning strategies and results of recent operations. In the event that the Company 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 Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income tax.

The Company records uncertain tax positions on the basis of a two-step process whereby the Company 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 Company recognizes the largest amount of tax benefit that is greater than 50% likely to be realized upon ultimate settlement with the tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within the Income tax expense (benefit) line in the Consolidated Statements of Operations. Accrued interest and penalties are included within the related tax liability line in the Consolidated Balance Sheets.

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

Recent Accounting Pronouncements

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

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

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

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

In November 2018, the FASB issued ASU No. 2018-18, "*Clarifying the Interaction Between Topic 808 and Topic 606"* (ASU 2018-18). The main provisions of ASU 2018-18 include: (i) clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue 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 revenue. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606 (January 1, 2018 for the Company) and early adoption is permitted. The Company is currently evaluating the impact of ASU 2018-18 on the Company's consolidated results of operations, financial position and disclosures.

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

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

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

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

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

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

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

(1) Amounts may not add due to rounding.

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

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

NOTE 3. DISCONTINUED OPERATIONS AND DIVESTITURES

Astora

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

The following table provides the operating results of Astora Discontinued operations, net of tax, for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Revenue	$ —	$ 338	$ 30,101
Litigation-related and other contingencies, net	$ 34,000	$ 775,474	$ 20,115
Asset impairment charges	$ —	$ —	$ 21,328
Loss from discontinued operations before income taxes	$ (69,702)	$ (816,426)	$ (123,164)
Income tax benefit	$ —	$ (13,704)	$ —
Discontinued operations, net of tax	$ (69,702)	$ (802,722)	$ (123,164)

Substantially all of the amounts reported in the table above as Litigation-related and other contingencies, net relate to charges for vaginal-mesh-related matters, which are further described in Note 15. Commitments and Contingencies. Loss from discontinued operations before income taxes also includes mesh-related legal defense costs, restructuring-related costs and certain other items.

The cash flows from discontinued operating activities related to Astora included the impact of net losses of $69.7 million, $802.7 million and $123.2 million for the years ended December 31, 2018, 2017 and 2016, respectively, and the impact of cash activity related to vaginal mesh cases. There were no material net cash flows related to Astora discontinued investing activities during the years ended December 31, 2018, 2017 and 2016. There was no depreciation or amortization during the years ended December 31, 2018, 2017 or 2016 related to Astora.

Astora Restructuring Initiative

The Astora wind-down process included a restructuring initiative implemented in 2016, which included a reduction of the Astora workforce consisting of approximately 250 employees (the Astora Restructuring Initiative).

A summary of expenses related to the Astora Restructuring Initiative is included below for the year ended December 31, 2016 (in thousands):

	2016
Employee separation, retention and other benefit-related costs	$ 20,476
Asset impairment charges	21,328
Contract termination-related items	8,074
Other wind-down costs	10,972
Total	$ 60,850

These restructuring costs are included in Discontinued operations in the Consolidated Statements of Operations. The Company did not incur any pre-tax charges during the years ended December 31, 2018 or 2017 as a result of the Astora Restructuring Initiative and the Company anticipates there will be no significant additional pre-tax restructuring expenses. The majority of these actions were completed as of September 30, 2016.

Litha

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

Somar

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

NOTE 4. RESTRUCTURING

Set forth below are disclosures relating to restructuring initiatives that resulted in material expenses or cash expenditures during any of the years ended December 31, 2018, 2017 or 2016 or had material restructuring liabilities at either December 31, 2018 or December 31, 2017. Employee separation, retention and certain other employee benefit-related costs related to our restructurings are expensed ratably over the requisite service period. Other restructuring costs are generally expensed as incurred.

2016 U.S. Generic Pharmaceuticals Restructuring Initiative

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

As a result of the 2016 U.S. Generic Pharmaceuticals Restructuring Initiative, the Company incurred pre-tax charges of $1.0 million and $173.9 million during the years ended December 31, 2017 and 2016, respectively. The Company did not incur any pre-tax restructuring expenses related to this initiative during the year ended December 31, 2018.

The 2017 charges related primarily to employee separation and other benefit-related costs.

The 2016 charges consisted of certain asset impairment charges of $107.2 million, charges to increase excess inventory reserves of $33.3 million, charges related to employee separation, retention and other benefit-related costs of $17.0 million, accelerated depreciation of $10.2 million and other charges of $6.2 million.

These charges are included in the U.S. Generic Pharmaceuticals segment and are included in Asset impairment charges, Cost of revenues and Selling, general and administrative expenses in the Consolidated Statements of Operations. The Company does not expect to incur additional significant expenses related to this restructuring initiative.

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

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

In December 2016, the Company 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 Company restructured its U.S. Branded - Specialty & Established Pharmaceuticals segment sales organization during the fourth quarter of 2016 (the 2016 U.S. Branded - Specialty & Established Pharmaceuticals Restructuring Initiative), which included the elimination of an approximate 375-member U.S. Branded - Specialty & Established Pharmaceuticals pain field sales force and the termination of certain contracts.

The Company incurred total pre-tax charges of approximately $61.5 million during the fourth quarter of 2016. These charges consisted of a non-cash intangible asset impairment charge of approximately $36.8 million, employee separation and other benefit-related costs of $16.5 million, early contract termination fees of $5.2 million and $3.0 million of inventory write-offs. These charges are included in the U.S. Branded - Specialty & Established Pharmaceuticals segment and are included in Asset impairment charges, Cost of revenues, and Selling, general and administrative expenses in the Consolidated Statements of Operations.

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

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

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

January 2017 Restructuring Initiative

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

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

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

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

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

2017 U.S. Generic Pharmaceuticals Restructuring Initiative

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

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

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

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

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

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

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

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

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

January 2018 Restructuring Initiative

In January 2018, the Company initiated a restructuring initiative that included a reorganization of its U.S. Generic Pharmaceuticals segment's research and development network, a further simplification of the Company'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 Company incurred pre-tax charges of $23.5 million and $2.6 million during the years ended December 31, 2018 and 2017, respectively.

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

The expenses in 2017 consisted of certain property, plant and equipment impairment charges of $2.0 million and certain other charges of $0.6 million. These charges are primarily included in the U.S. Generic Pharmaceuticals segment.

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

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

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

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

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

NOTE 5. ACQUISITIONS

VOLTAREN® Gel

The Company had exclusive U.S. marketing rights to VOLTAREN® Gel through June 30, 2016 pursuant to a License and Supply Agreement entered into in 2008 with and among Novartis AG and Novartis Consumer Health, Inc. (the 2008 VOLTAREN® Gel Agreement). On December 11, 2015, the Company, Novartis AG and Sandoz Inc. entered into a new License and Supply Agreement (the 2015 VOLTAREN® Gel Agreement) whereby the Company licensed exclusive U.S. marketing and license rights to commercialize VOLTAREN® Gel and to launch an authorized generic of VOLTAREN® Gel effective July 1, 2016. Pursuant to the 2015 VOLTAREN® Gel Agreement, the former 2008 VOLTAREN® Gel Agreement expired on June 30, 2016 in accordance with its terms.

The Company accounted for this transaction as a business combination as of the effective date in accordance with the relevant accounting literature. The Company acquired the product for consideration of approximately $162.7 million, consisting of an upfront payment of $16.2 million and contingent cash consideration with an acquisition-date fair value of approximately $146 million, including the impact of a measurement period adjustment recorded during the fourth quarter of 2016. See Note 7. Fair Value Measurements for further discussion of this contingent consideration.

The preliminary fair values of the net identifiable assets acquired totaled approximately $162.7 million, resulting in no goodwill. The amount of net identifiable assets acquired in connection with the VOLTAREN® Gel acquisition includes approximately $162.7 million of identifiable developed technology intangible assets to be amortized over an initial average life of approximately 7 years.

The operating results of VOLTAREN® Gel under business combination accounting are included in the accompanying Consolidated Statements of Operations for the years ended December 31, 2018 and 2017 and for the six months ended December 31, 2016. The results included in the accompanying Consolidated Statements of Operations for the six months ended June 30, 2016, were accounted for under the previous license and supply agreement, which was not treated as a business combination.

Pro forma results of operations have not been presented because the effect of the 2015 VOLTAREN® Gel Agreement was not material. The estimates of the fair values of the net assets acquired were finalized and all measurement period adjustments were complete as of December 31, 2016.

NOTE 6. SEGMENT RESULTS

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

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

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

We evaluate segment performance based on each segment’s adjusted income 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; inventory step-up recorded as part of our acquisitions; litigation-related and other contingent matters; gains or losses from early termination of debt; gains or losses from the sales of businesses and other assets; foreign currency gains or losses on intercompany financing arrangements; and certain other items.

Certain of the corporate expenses incurred by the Company are not attributable to any specific segment. Accordingly, these costs are not allocated to any of the Company’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 Company’s segments. The Company’s consolidated adjusted income from continuing operations before income tax is equal to the combined results of each of its segments less these unallocated corporate items.

U.S. Branded - Specialty & Established Pharmaceuticals

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

U.S. Branded - Sterile Injectables

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

U.S. Generic Pharmaceuticals

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

International Pharmaceuticals

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

The following represents selected information for the Company's reportable segments for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Net revenues from external customers:			
U.S. Branded - Specialty & Established Pharmaceuticals	$ 862,832	$ 957,525	$ 1,166,294
U.S. Branded - Sterile Injectables	929,566	750,471	576,399
U.S. Generic Pharmaceuticals	1,012,215	1,530,530	1,988,214
International Pharmaceuticals (1)	142,465	230,332	279,367
Total net revenues from external customers	$ 2,947,078	$ 3,468,858	$ 4,010,274
Adjusted income from continuing operations before income tax:			
U.S. Branded - Specialty & Established Pharmaceuticals	$ 368,790	$ 485,515	$ 553,806
U.S. Branded - Sterile Injectables	695,363	563,103	426,170
U.S. Generic Pharmaceuticals	317,892	501,249	653,309
International Pharmaceuticals	59,094	58,308	84,337
Total segment adjusted income from continuing operations before income tax	$ 1,441,139	$ 1,608,175	$ 1,717,622

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

The table below provides reconciliations of our Total consolidated loss from continuing operations before income tax, which is determined in accordance with U.S. generally accepted accounting principles (U.S. GAAP), to our total segment adjusted income from continuing operations before income tax for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Total consolidated loss from continuing operations before income tax	$ (938,832)	$ (1,483,004)	$ (3,923,856)
Interest expense, net	521,656	488,228	452,679
Corporate unallocated costs (1)	200,592	165,298	189,043
Amortization of intangible assets	622,339	773,766	876,451
Inventory step-up and certain manufacturing costs that will be eliminated pursuant to integration plans	261	390	125,699
Upfront and milestone payments to partners	45,108	9,483	8,330
Separation benefits and other cost reduction initiatives (2)	86,295	212,448	107,491
Impact of VOLTAREN® Gel generic competition	—	—	(7,750)
Certain litigation-related and other contingencies, net (3)	13,809	185,990	23,950
Asset impairment charges (4)	916,939	1,154,376	3,781,165
Acquisition-related and integration items (5)	21,914	58,086	87,601
Loss on extinguishment of debt	—	51,734	—
Foreign currency impact related to the remeasurement of intercompany debt instruments	(5,486)	(1,403)	366
Other, net (6)	(43,456)	(7,217)	(3,547)
Total segment adjusted income from continuing operations before income tax	$ 1,441,139	$ 1,608,175	$ 1,717,622

(1) Amounts include certain corporate overhead costs, such as headcount, facility and corporate litigation expenses and certain other income and expenses.
(2) Amounts in 2018 primarily relate to employee separation costs of $31.7 million, accelerated depreciation of $35.2 million, charges to increase excess inventory reserves of $2.9 million and other charges of $16.5 million, each of which related primarily to our restructuring initiatives. Amounts in 2017 primarily relate to employee separation costs of $53.0 million, accelerated depreciation of $123.7 million, charges to increase excess inventory reserves of $13.7 million and other charges of $22.0 million. These charges were related primarily to the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative. Amounts in 2016 primarily relate to employee separation costs of $60.2 million, charges to increase excess inventory reserves of $24.5 million and other restructuring costs of $25.1 million, consisting primarily of contract termination fees and building costs. See Note 4. Restructuring for discussion of our material restructuring initiatives.
(3) Amounts include adjustments for Litigation-related and other contingencies, net as further described in Note 15. 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 property, plant and equipment as further described in Note 4. Restructuring, Note 7. Fair Value Measurements and Note 9. Property, Plant and Equipment.
(5) Amounts include charges due to changes in the fair value of contingent consideration of $19.9 million, $49.9 million and $23.8 million, respectively. All other amounts are directly related to costs associated with acquisition and integration efforts.
(6) Amounts in 2018 primarily relate to gains on sales of businesses and other assets, as further described in Note 19. Other Income, Net.

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

	2018	2017	2016
U.S. Branded - Specialty & Established Pharmaceuticals:			
Specialty Products:			
XIAFLEX®	$ 264,638	$ 213,378	$ 189,689
SUPPRELIN® LA	81,707	86,211	78,648
Other Specialty (1)	156,607	153,384	138,483
Total Specialty Products	$ 502,952	$ 452,973	$ 406,820
Established Products:			
PERCOCET®	$ 122,901	$ 125,231	$ 139,211
VOLTAREN® Gel	57,700	68,780	100,642
OPANA® ER	—	83,826	158,938
Other Established (2)	179,279	226,715	360,683
Total Established Products	$ 359,880	$ 504,552	$ 759,474
Total U.S. Branded - Specialty & Established Pharmaceuticals (3)	$ 862,832	$ 957,525	$ 1,166,294
U.S. Branded - Sterile Injectables:			
VASOSTRICT®	$ 453,767	$ 399,909	$ 343,468
ADRENALIN®	143,489	76,523	22,172
Ertapenem for injection	57,668	—	—
Other Sterile Injectables (4)	274,642	274,039	210,759
Total U.S. Branded - Sterile Injectables (3)	$ 929,566	$ 750,471	$ 576,399
Total U.S. Generic Pharmaceuticals (5)	$ 1,012,215	$ 1,530,530	$ 1,988,214
Total International Pharmaceuticals (6)	$ 142,465	$ 230,332	$ 279,367
Total Revenues	$ 2,947,078	$ 3,468,858	$ 4,010,274

(1) Products included within Other Specialty include NASCOBAL® Nasal Spray, TESTOPEL® and AVEED®.
(2) Products included within Other Established include, but are not limited to, LIDODERM®, FORTESTA® Gel, EDEX® and TESTIM® including the authorized generics of TESTIM® and FORTESTA® Gel.
(3) Individual products presented above represent the top two performing products in each product category and/or any product having revenues in excess of $100 million during any of the years ended December 31, 2018, 2017 and 2016 or $25 million during any quarterly period in 2018.
(4) Products included within Other Sterile Injectables include, but are not limited to, APLISOL® and ephedrine sulfate injection.
(5) The U.S. Generic Pharmaceuticals segment is comprised of a portfolio of products that are generic versions of branded products, are distributed primarily through the same wholesalers, generally have no intellectual property protection and are sold within the U.S. Combined sales of ezetimibe tablets and quetiapine ER tablets, for which we lost temporary marketing exclusivity during the second quarter of 2017, made up 7% of consolidated total revenue in both 2017 and 2016. No other individual product within this segment has exceeded 5% of consolidated total revenues for the periods presented.
(6) The International Pharmaceuticals segment, which accounted for 5%, 7% and 7% of consolidated total revenues in 2018, 2017 and 2016, respectively, includes a variety of specialty pharmaceutical products sold outside the U.S., primarily in Canada through our operating company Paladin. This segment also included Litha, which was sold in July 2017, and Somar, which was sold in October 2017.

The following represents depreciation expense for our reportable segments for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
U.S. Branded - Specialty & Established Pharmaceuticals	$ 14,542	$ 16,957	$ 16,294
U.S. Branded - Sterile Injectables	10,500	8,411	9,023
U.S. Generic Pharmaceuticals	66,016	174,652	70,816
International Pharmaceuticals	4,925	3,332	2,557
Corporate unallocated	5,385	6,647	8,168
Total depreciation expense	$ 101,368	$ 209,999	$ 106,858

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

NOTE 7. FAIR VALUE MEASUREMENTS

Financial Instruments

The financial instruments recorded in our Consolidated Balance Sheets include cash and cash equivalents (including money market funds and time deposits), restricted cash and cash equivalents, accounts receivable, marketable securities, equity and cost method investments, accounts payable and accrued expenses, acquisition-related contingent consideration and debt obligations. Included in cash and cash equivalents and restricted cash and cash equivalents 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 and cash equivalents (including money market funds and time deposits), accounts receivable, accounts payable and accrued expenses approximate their fair values.

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

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

(1) These amounts are reported in our Consolidated Balance Sheets as Restricted cash and cash equivalents.
(2) These amounts are reported in our Consolidated Balance Sheets as Other assets.
(3) Approximately $299.7 million and $313.8 million of our restricted cash and cash equivalents are held in qualified settlement funds (QSFs) for mesh-related matters at December 31, 2018 and December 31, 2017, respectively. The remaining amount of restricted cash and cash equivalents at December 31, 2018 primarily relates to other litigation-related matters. See Note 15. Commitments and Contingencies for further information.

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

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

Marketable Securities

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

Acquisition-Related Contingent Consideration

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

Recurring Fair Value Measurements

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

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

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

At December 31, 2018 and December 31, 2017, money market funds include $86.9 million and $35.6 million, respectively, in QSFs to be disbursed to mesh-related or other product liability claimants. Amounts in QSFs are considered restricted cash equivalents. See Note 15. Commitments and Contingencies for further discussion of our product liability cases. At December 31, 2018 and December 31, 2017, the differences between the amortized cost and the fair value of our money market funds and equity securities, as well as the related gross unrealized gains or losses, were not material, individually or in the aggregate.

Fair Value Measurements Using Significant Unobservable Inputs

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

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

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

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

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

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

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

Nonrecurring Fair Value Measurements

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

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

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

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

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

Additionally, the Company recorded aggregate pre-tax non-cash goodwill impairment charges during the years ended December 31, 2018 and 2017 of $680.0 million and $288.7 million, respectively. Refer to Note 10. Goodwill and Other Intangibles for further description, including the valuation methodologies utilized.

NOTE 8. INVENTORIES

Inventories consist of the following at December 31, 2018 and December 31, 2017 (in thousands):

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

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

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

NOTE 9. PROPERTY, PLANT AND EQUIPMENT

Changes in the amount of Property, plant and equipment for the year ended December 31, 2018 are set forth in the table below (in thousands).

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

Depreciation expense, including expense related to assets under capital lease, was $101.4 million, $210.0 million and $106.9 million for the years ended December 31, 2018, 2017 and 2016, respectively.

During the years ended December 31, 2018, 2017 and 2016, the Company recorded impairment charges totaling $6.5 million, $65.7 million and $15.9 million, respectively. These charges are included in the Asset impairment charges line item in our Consolidated Statement of Operations.

In 2018 and 2016, impairment charges reflect the write-off of certain property, plant and equipment, including amounts that were abandoned or sold as part of our ongoing efforts to improve our operating efficiency and consolidate certain locations.

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

NOTE 10. GOODWILL AND OTHER INTANGIBLES

Goodwill

Changes in the carrying amount of our goodwill for the years ended December 31, 2018 and 2017 were as follows (in thousands):

	U.S. Branded - Specialty & Established Pharmaceuticals	U.S. Branded - Sterile Injectables	U.S. Generic Pharmaceuticals	International Pharmaceuticals	Total
Goodwill as of December 31, 2016	$ 1,009,248	$ —	$ 3,531,301	$ 188,846	$ 4,729,395
Effect of currency translation	—	—	—	9,431	9,431
Goodwill impairment charges	(180,430)	—	—	(108,314)	(288,744)
Goodwill as of December 31, 2017	$ 828,818	$ —	$ 3,531,301	$ 89,963	$ 4,450,082
Allocation to current segments (1)	—	2,731,193	(2,731,193)	—	—
Effect of currency translation	—	—	—	(5,446)	(5,446)
Goodwill impairment charges	—	—	(649,000)	(31,000)	(680,000)
Goodwill as of December 31, 2018	$ 828,818	$ 2,731,193	$ 151,108	$ 53,517	$ 3,764,636

(1) This allocation relates to the change in segments described in Note 6. Segment Results. The amount of goodwill initially attributed to the new U.S. Branded - Sterile Injectables and U.S. Generic Pharmaceuticals segments was determined using a relative fair value methodology in accordance with U.S. GAAP.

The carrying amounts of goodwill at December 31, 2018 and December 31, 2017 are net of the following accumulated impairments (in thousands):

	U.S. Branded - Specialty & Established Pharmaceuticals	U.S. Branded - Sterile Injectables	U.S. Generic Pharmaceuticals	International Pharmaceuticals	Total
Accumulated impairment losses as of December 31, 2017	$ 855,810	$ —	$ 2,342,549	$ 463,545	$ 3,661,904
Accumulated impairment losses as of December 31, 2018	$ 855,810	$ —	$ 2,991,549	$ 456,408	$ 4,303,767

Other Intangible Assets

Changes in the amount of other intangible assets for the year ended December 31, 2018 are set forth in the table below (in thousands).

Cost basis:	Balance as of December 31, 2017	Acquisitions	Impairments	Other (1)	Effect of Currency Translation	Balance as of December 31, 2018
Indefinite-lived intangibles:						
In-process research and development	$ 347,200	$ —	$ (87,900)	$ (165,400)	$ —	$ 93,900
Total indefinite-lived intangibles	$ 347,200	$ —	$ (87,900)	$ (165,400)	$ —	$ 93,900
Finite-lived intangibles:						
Licenses (weighted average life of 12 years)	$ 457,402	$ —	$ —	$ —	$ —	$ 457,402
Tradenames	6,409	—	—	—	—	6,409
Developed technology (weighted average life of 11 years)	6,187,764	3,000	(142,518)	154,753	(20,984)	6,182,015
Total finite-lived intangibles (weighted average life of 11 years)	$ 6,651,575	$ 3,000	$ (142,518)	$ 154,753	$ (20,984)	$ 6,645,826
Total other intangibles	$ 6,998,775	$ 3,000	$ (230,418)	$ (10,647)	$ (20,984)	$ 6,739,726

Accumulated amortization:	Balance as of December 31, 2017	Amortization	Impairments	Other (1)	Effect of Currency Translation	Balance as of December 31, 2018
Finite-lived intangibles:						
Licenses	$ (370,221)	$ (27,961)	$ —	$ —	$ —	$ (398,182)
Tradenames	(6,409)	—	—	—	—	(6,409)
Developed technology	(2,304,461)	(594,378)	—	10,647	10,363	(2,877,829)
Total other intangibles	$ (2,681,091)	$ (622,339)	$ —	$ 10,647	$ 10,363	$ (3,282,420)
Net other intangibles	$ 4,317,684					$ 3,457,306

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

Amortization expense for the years ended December 31, 2018, 2017 and 2016 totaled $622.3 million, $773.8 million and $876.5 million, respectively. Amortization expense is included in Cost of revenues in the Consolidated Statements of Operations. Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2018 is as follows (in thousands):

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

Impairments

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

As part of our goodwill and intangible asset impairment assessments, we estimate the fair values of our reporting units and our intangible assets using an income approach that utilizes a discounted cash flow model or, where appropriate, a market approach. The discounted cash flow models are dependent upon our estimates of future cash flows and other factors. These estimates of future cash flows involve assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, tax rates, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The discount rates applied to the estimated cash flows for the Company's October 1, 2018, 2017 and 2016 annual goodwill and indefinite-lived intangible assets impairment test ranged from 9.5% to 11.5%, from 9.5% to 12.5% and from 8.5% to 11.0%, 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 Statements of Operations.

During the years ended December 31, 2018, 2017 and 2016, the Company incurred the following goodwill and other intangible asset impairment charges (in thousands):

	2018	2017	2016
Goodwill impairment charges	$ 680,000	$ 288,745	$ 2,676,350
Other intangible asset impairment charges	$ 230,418	$ 799,955	$ 1,088,903

A summary of significant goodwill and other intangible asset impairment tests and related charges is included below. Other pre-tax non-cash intangible asset impairment charges that are not included in the below narrative totaled $230.4 million, $586.9 million and $862.0 million during the years ended December 31, 2018, 2017 and 2016, respectively. These charges relate primarily to certain in-process research and development and/or developed technology intangible assets that were tested for impairment following changes in market conditions and certain other factors impacting recoverability.

Annual Goodwill Impairment Tests

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

The U.S. Generic Pharmaceuticals impairment can be primarily attributed to an increase in the discount rate used in the determination of fair value and unfavorable underlying business outlook assumption changes. The Paladin impairment was primarily a result of increased competition and slower than expected product launches in our Canadian market. We did not record goodwill impairment charges for the other reporting units as a result of the annual tests.

As a result of our annual test performed as of October 1, 2017, the Company determined that the estimated fair values of its Branded, Generics and Paladin reporting units exceeded their carrying amounts; therefore, no related goodwill impairment charge was required.

Certain of our 2016 impairment charges discussed below related to our 2016 annual goodwill impairment test. After performing this test, we concluded that the carrying amounts of our Generics, Paladin, Somar and Litha reporting units each exceeded their respective estimated fair values and recorded goodwill impairment charges of $2,342.5 million, $272.6 million, $33.0 million and $26.3 million, respectively. The impairments were a result of a combination of factors, including increased buying power from the continued consolidation of our generic business customer base, a significant change in the value derived from the level and frequency of anticipated future pricing opportunities and increased levels of competition, particularly in our Generics reporting unit, due to the entry of new low cost competitors and accelerated FDA ANDA approvals. These factors were exacerbated by an increase in the risk factor included in the discount rate used to calculate the Generics discounted cash flows since the date of the preceding interim test. The increase in the discount rate was due to the implied control premium resulting from recent trading values of our stock. On a combined basis, these factors reduced the estimated fair value of our reporting units.

Other Impairment Tests

Our first quarter 2018 change in segments described in Note 6. Segment Results resulted in changes to our reporting units for goodwill impairment testing purposes, including the creation of a new U.S. Branded - Sterile Injectables reporting unit, which was previously part of our Generics reporting unit. As a result of these changes, under U.S. GAAP, we tested the goodwill of the former Generics reporting unit immediately before the segment realignment and the goodwill of both the new U.S. Branded - Sterile Injectables and U.S. Generic Pharmaceuticals reporting units immediately after the segment realignment. These goodwill tests were performed using an income approach that utilizes a discounted cash flow model. The results of these goodwill impairment tests were as follows:

- The former Generics reporting unit's estimated fair value (determined using a discount rate of 9.5%) exceeded its carrying amount, resulting in no related goodwill impairment charge.

- The new U.S. Branded - Sterile Injectables reporting unit's estimated fair value (determined using a discount rate of 9.5%) exceeded its carrying amount, resulting in no related goodwill impairment charge.
- The new U.S. Generic Pharmaceuticals reporting unit's carrying amount exceeded its estimated fair value (determined using a discount rate of 9.5%), resulting in a pre-tax non-cash goodwill impairment charge of $391.0 million.

In March 2017, we announced that the FDA's Drug Safety and Risk Management and Anesthetic and Analgesic Drug Products Advisory Committees voted that the benefits of reformulated OPANA® ER (oxymorphone hydrochloride extended release) no longer outweigh its risks. In June 2017, we became aware of the FDA's request that we voluntarily withdraw OPANA® ER from the market and, in July 2017, after careful consideration and consultation with the FDA, we decided to voluntarily remove OPANA® ER from the market. As a result of our decision, the Company determined that the carrying amount of its OPANA® ER intangible asset was no longer recoverable, resulting in a pre-tax, non-cash impairment charge of $20.6 million in the second quarter of 2017, representing the remaining carrying amount.

As a result of the withdrawal of OPANA® ER from the market and the continued erosion of our U.S. Branded - Specialty & Established Pharmaceuticals segment's Established Products portfolio, we initiated an interim goodwill impairment analysis of our Branded reporting unit during the second quarter of 2017. We recorded a pre-tax, non-cash goodwill impairment charge of $180.4 million during the three months ended June 30, 2017 for the amount by which the reporting unit's carrying amount exceeded its fair value. We estimated the fair value of the Branded reporting unit using an income approach that utilized a discounted cash flow model. The discount rate applied to the estimated cash flows for our Branded goodwill impairment test was 9.5%.

Following the announcement of the 2017 U.S. Generic Pharmaceuticals Restructuring Initiative, which is further described in Note 4. Restructuring, the Company assessed the recoverability of certain products that were discontinued as part of this initiative, resulting in pre-tax, non-cash intangible asset impairment charges of approximately $57.5 million during the second quarter of 2017.

Pursuant to an existing agreement with a wholly owned subsidiary of Novartis AG (Novartis), Paladin licensed the Canadian rights to commercialize serelaxin, an investigational drug for the treatment of acute heart failure (AHF). In March 2017, Novartis announced that a Phase 3 study of serelaxin in patients with AHF failed to meet its primary endpoints. As a result, we concluded that the full carrying amount of our serelaxin in-process research and development intangible asset was impaired, resulting in a $45.5 million pre-tax non-cash impairment charge during the three months ended March 31, 2017. In addition, and as a result of the serelaxin impairment, we assessed the recoverability of our Paladin goodwill balance and determined that the estimated fair value of the Paladin reporting unit was below its carrying amount. We recorded a pre-tax, non-cash goodwill impairment charge of $82.6 million during the three months ended March 31, 2017 for the amount by which the carrying amount exceeded the reporting unit's fair value. We estimated the fair value of the Paladin reporting unit using an income approach that utilized a discounted cash flow model. The discount rate applied to the estimated cash flows for our Paladin goodwill impairment test was 10.0%.

As further discussed in Note 3. Discontinued Operations and Divestitures, we entered into a definitive agreement to sell Somar on June 30, 2017, which resulted in Somar's assets and liabilities being classified as held for sale. The initiation of held-for-sale accounting, together with the agreed upon sale price, triggered an impairment review. Accordingly, we performed an impairment analysis using a market approach and determined that impairment charges were required. We recorded pre-tax, non-cash impairment charges of $25.7 million and $89.5 million related to Somar's goodwill and other intangible assets, respectively, during the second quarter of 2017, each of which represented the remaining carrying amounts of the corresponding assets.

During the first quarter of 2016, the Company recognized pre-tax, non-cash asset impairment charges of $100.3 million related to the 2016 U.S. Generic Pharmaceuticals Restructuring Initiative, which resulted from the discontinuation of certain commercial products and the abandonment of certain IPR&D projects. See Note 4. Restructuring for discussion of our material restructuring initiatives.

As a result of unfavorable formulary changes and generic competition for sumatriptan, we experienced a downturn in the performance of our SUMAVEL® DOSEPRO® product in 2016, which is a needle-free delivery system for sumatriptan acquired from Zogenix, Inc. in 2014. As a result of this underperformance, we concluded during the third quarter of 2016 that an impairment assessment was required to evaluate the recoverability of SUMAVEL® DOSEPRO®. After performing this assessment, we recorded a pre-tax, non-cash intangible asset impairment charge of $72.8 million during the third quarter of 2016, representing the remaining carrying amount.

During the third quarter of 2016, we determined that we would not pursue commercialization of a product in certain international markets. Accordingly, we tested the finite-lived intangible asset associated with this product for impairment and determined that the carrying amount was no longer fully recoverable, resulting in a pre-tax, non-cash intangible asset impairment charge of $16.2 million during the third quarter of 2016.

During the fourth quarter of 2016, we recognized a pre-tax, non-cash intangible asset impairment charge of $37.6 million resulting primarily from the termination of our BELBUCA™ product and the return of this product to BDSI. We also recognized a pre-tax, non-cash goodwill impairment charge of $1.9 million at this time, primarily relating to BELBUCA™.

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

BioSpecifics Technologies Corp.

The Company, through an affiliate, is party to a development and license agreement, as amended (the BioSpecifics Agreement) with BioSpecifics Technologies Corp. (BioSpecifics). The BioSpecifics Agreement was originally entered into in June 2004 to obtain exclusive worldwide rights to develop, market and sell certain products containing BioSpecifics' enzyme CCH, which we market for approved indications under the trademark XIAFLEX®. The Company's licensed rights concern the development and commercialization of products, other than dermal formulations labeled for topical administration, and currently, the Company's licensed rights cover the indications of Dupuytren's contracture (DC), Dupuytren's nodules, Peyronie's disease (PD), adhesive capsulitis, cellulite, canine and human lipomas, plantar fibromatosis, lateral hip fat and other potential aesthetic indications. The Company may further expand the BioSpecifics Agreement, at its option, to cover other indications as they are developed by the Company or BioSpecifics.

Under the BioSpecifics Agreement, we are responsible, at our own cost and expense, for developing the formulation and finished dosage form of products and arranging for the clinical supply of products. BioSpecifics is currently conducting exploratory clinical trials evaluating CCH as a treatment for a number of conditions, including uterine fibroids. The Company has the option to license development and marketing rights to these indications based on a full analysis of the data from the clinical trials, which would transfer responsibility for the future development costs to the Company 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 Company or its sublicensees, including Asahi Kasei Pharma Corporation and Swedish Orphan Biovitrum AB. We are also obligated to pay a percentage of any future regulatory or commercial milestone payments received from such sublicensees. In addition, the Company 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 Company and its affiliates.

Other

During the second quarter of 2018, we entered into a development, license and commercialization agreement with a third party pharmaceutical company related to five sterile injectable product candidates. Pursuant to this agreement, the third party will generally be responsible, at its expense, to develop and seek regulatory approval for these product candidates, and the Company will generally be responsible, at its expense, to launch and distribute any products that are approved. The Company 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 Company became obligated to make an upfront payment, which was recorded as Research and development expense in the Consolidated Statements of Operations during the three months ended June 30, 2018. The Company could become obligated to make additional payments based on certain potential future milestones being achieved.

NOTE 12. CONTRACT ASSETS AND LIABILITIES

Our revenue consists almost entirely of sales of our pharmaceutical products to customers, whereby we ship products to a customer pursuant to a purchase order. Revenue contracts such as these do not generally give rise to contract assets or contract liabilities because: (i) the underlying contracts generally have only a single performance obligation and (ii) we do not generally receive consideration until the performance obligation is fully satisfied. At December 31, 2018, the unfulfilled performance obligations for these types of contracts relate to ordered but undelivered products. We generally expect to fulfill the performance obligations and recognize revenue 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 revenue-generating contracts, including license and collaboration agreements, may result in contract assets and/or contract liabilities. For example, we may recognize contract liabilities upon receipt of certain upfront and milestone payments from customers when there are remaining performance obligations.

The following table shows the opening and closing balances of contract assets and contract liabilities from contracts with customers (dollars in thousands):

	December 31, 2018	January 1, 2018	$ Change	% Change
Contract assets, net (1)	$ 12,065	$ 11,287	$ 778	7 %
Contract liabilities, net (2)	$ 19,217	$ 20,954	$ (1,737)	(8)%

_____

(1) At December 31, 2018 and January 1, 2018, approximately $9.3 million and $8.2 million, respectively, of these contract asset amounts are classified as current assets and are included in Prepaid expenses and other current assets in the Company's Consolidated Balance Sheets. The remaining amounts are classified as non-current and are included in Other assets. The net increase in contract assets during the year ended December 31, 2018 was primarily due to certain sales activity during the period, partially offset by reclassifications to accounts receivable following the resolution of certain conditions other than the passage of time affecting the Company's rights to consideration for the sale of certain goods.

(2) At December 31, 2018 and January 1, 2018, approximately $1.7 million and $1.9 million, respectively, of these contract liability amounts are classified as current liabilities and are included in Accounts payable and accrued expenses in the Company's Consolidated Balance Sheets. The remaining amounts are classified as non-current and are included in Other liabilities. During the year ended December 31, 2018, the Company recognized revenue of $1.7 million that was included in the contract liability balance at January 1, 2018, resulting in a corresponding decrease in contract liabilities.

During the year ended December 31, 2018, we recognized revenue of $2.8 million relating to performance obligations satisfied, or partially satisfied, in prior periods. Such revenue generally relates to changes in estimates with respect to our variable consideration.

NOTE 13. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses include the following at December 31, 2018 and December 31, 2017 (in thousands):

	December 31, 2018	December 31, 2017
Trade accounts payable	$ 96,024	$ 85,348
Returns and allowances	236,946	291,034
Rebates	144,860	168,333
Chargebacks	2,971	14,604
Accrued interest	130,182	130,257
Accrued payroll and related benefits	89,895	113,908
Accrued royalties and other distribution partner payables	122,028	63,114
Acquisition-related contingent consideration—short-term	36,514	70,543
Other	149,780	159,684
Total	$ 1,009,200	$ 1,096,825

NOTE 14. DEBT

The following table presents information about the Company's total indebtedness at December 31, 2018 and December 31, 2017 (dollars in thousands):

	December 31, 2018			December 31, 2017		
	Effective Interest Rate	Principal Amount	Carrying Amount	Effective Interest Rate	Principal Amount	Carrying Amount
7.25% Senior Notes due 2022	7.91%	$ 400,000	$ 392,947	7.91%	$ 400,000	$ 390,974
5.75% Senior Notes due 2022	6.04%	700,000	694,464	6.04%	700,000	692,855
5.375% Senior Notes due 2023	5.62%	750,000	743,438	5.62%	750,000	742,048
6.00% Senior Notes due 2023	6.28%	1,635,000	1,616,817	6.28%	1,635,000	1,613,446
5.875% Senior Secured Notes due 2024	6.14%	300,000	296,062	6.14%	300,000	295,513
6.00% Senior Notes due 2025	6.27%	1,200,000	1,183,415	6.27%	1,200,000	1,181,243
Term Loan B Facility Due 2024	7.02%	3,363,775	3,331,276	6.09%	3,397,925	3,360,103
Other debt		—	—	1.50%	55	55
Total long-term debt, net		$ 8,348,775	$ 8,258,419		$ 8,382,980	$ 8,276,237
Less current portion, net		34,150	34,150		34,205	34,205
Total long-term debt, less current portion, net		$ 8,314,625	$ 8,224,269		$ 8,348,775	$ 8,242,032

The obligations of the borrowers under the credit agreement are guaranteed by the Company and the subsidiaries of the Company (with certain customary exceptions). The unsecured senior notes are issued by certain of the Company's subsidiaries and are guaranteed on a senior unsecured basis by the subsidiaries of Endo International plc that also guarantee the credit agreement, except for a de minimis amount of the 7.25% Senior Notes due 2022, which are issued by Endo Health Solutions Inc. (EHSI) and guaranteed on a senior unsecured basis by the guarantors named in the Fifth Supplemental Indenture relating to such notes. The senior secured notes are issued by certain of the Company's subsidiaries and are guaranteed on a senior secured basis by Endo International plc and its subsidiaries that also guarantee the credit agreement. The obligations under (i) the credit agreement and related loan documents and (ii) the senior secured notes are secured on a *pari passu* basis by a perfected first priority (subject to certain permitted liens) lien on the collateral securing such instruments, which collateral represents substantially all of the assets of the issuers or borrowers and the guarantors party thereto (subject to customary exceptions). Our senior unsecured notes are unsecured and effectively subordinated in right of priority to our credit agreement and our senior secured notes, in each case to the extent of the value of the collateral securing such instruments.

The aggregate estimated fair value of the Company's long-term debt, which was estimated using inputs based on quoted market prices for the same or similar debt issuances, was $7.2 billion and $7.5 billion at December 31, 2018 and December 31, 2017, respectively. Based on this valuation methodology, we determined these debt instruments represent Level 2 measurements within the fair value hierarchy.

Credit Facilities

The Company and certain of its subsidiaries are party to a credit agreement (the Credit Agreement), which provides for (i) a senior secured revolving credit facility generally allowing for borrowings in a principal amount of up to $1,000.0 million (the Revolving Credit Facility) and (ii) a senior secured term loan facility in an initial principal amount of $3,415.0 million (the Term Loan Facility and, together with the Revolving Credit Facility, the Credit Facilities). We have $997.3 million of remaining credit available through the Revolving Credit Facility at December 31, 2018.

The Credit Agreement contains affirmative and negative covenants that the Company 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 Company's affiliates. As of December 31, 2018 and 2017, we were in compliance with all such covenants.

The Revolving Credit Facility generally matures in 2022. Principal payments on the Term Loan Facility equal to 0.25% of the initial principal amount are generally payable quarterly until the Term Loan Facility's maturity date in 2024. However, on an annual basis commencing with the year ended December 31, 2018, the Company is required to perform a calculation of Excess Cash Flow (as defined in the Credit Agreement), which could result in certain pre-payments of the principal relating to the Term Loan Facility in accordance with the terms of the Credit Agreement. No such payment is required at December 31, 2018. In addition, any outstanding amounts borrowed pursuant to the Credit Facilities will immediately mature if any of the following of our senior notes (other than, in the case of amounts borrowed pursuant to the Revolving Credit Facility, the 5.375% Senior notes due 2023 and the 6.00% Senior Notes due 2023) are not refinanced or repaid in full prior to the date that is 91 days prior to the stated maturity date thereof:

Instrument	Maturity Date
7.25% Senior Notes Due 2022	January 15, 2022
5.75% Senior Notes Due 2022	January 15, 2022
5.375% Senior Notes Due 2023	January 15, 2023
6.00% Senior Notes Due 2023	July 15, 2023

The Credit Agreement provides that the borrowers thereunder may incur (i) incremental revolving commitments and/or incremental term loans in an aggregate principal amount of up to: (a) up to $1.0 billion plus (b) an unlimited amount if the *pro forma* First Lien Net Leverage Ratio (as defined in the Credit Agreement) at the time of incurrence of such incremental commitments or loans after giving effect thereto is less than or equal to 2.50 to 1.00 (assuming for purposes of such calculation that any incremental revolving commitments being incurred are fully drawn and without netting cash proceeds of any incremental facilities or incremental equivalent debt) or, (ii) in lieu of incremental facilities under the Credit Agreement, incremental equivalent debt consisting of *pari passu* notes or loans (subject to *pro forma* compliance with a First Lien Net Leverage Ratio of 2.50 to 1.00), junior secured notes or loans (subject to *pro forma* compliance with a Secured Net Leverage Ratio (as defined in the Credit Agreement) of 3.50 to 1.00) or unsecured notes or loans (subject to *pro forma* compliance with a Total Net Leverage Ratio (as defined in the Credit Agreement) of 6.50 to 1.00), subject, in each case, to compliance by the borrowers with the documentation and other requirements under the Credit Agreement, without the need for consent from any of the existing lenders under the Credit Agreement.

Borrowings under the Revolving Credit Facility bear interest, at the borrower's election, at a rate equal to (i) an applicable margin between 1.50% and 3.00% depending on the Company's Total Net Leverage Ratio plus the London Interbank Offered Rate (LIBOR) or (ii) an applicable margin between 0.50% and 2.00% depending on the Company's Total Net Leverage Ratio plus the Alternate Base Rate (as defined in the Credit Agreement). In addition, borrowings under our Term Loan Facility bear interest, at the borrower's election, at a rate equal to (i) 4.25% plus LIBOR, subject to a LIBOR floor of 0.75%, or (ii) 3.75% plus the Alternate Base Rate, subject to an Alternate Base Rate floor of 1.75%.

Senior Notes and Senior Secured Notes

Our various senior notes and senior secured notes mature between 2022 and 2025. The indentures governing these notes generally allow for redemption prior to maturity, in whole or in part, subject to certain restrictions and limitations described therein, in the following ways:

- Until a date specified in each indenture (the Non-Call Period), the notes may be redeemed, in part or in full, by paying the sum of: (i) 100% of the principal amount being redeemed, (ii) an applicable make-whole premium as described in each indenture and (iii) accrued and unpaid interest. As of December 31, 2018, the Non-Call Period has expired for each of our notes except for the 5.875% Senior Secured Notes due 2024 (the 2024 Notes) and the 6.00% Senior Notes due 2025.
- After the Non-Call Period specified in each indenture, the notes may be redeemed, in whole or in part, at redemption prices set forth in each indenture, plus accrued and unpaid interest. The redemption prices for each of our notes vary over time. The redemption prices pursuant to this clause range from 101.208% to 104.500% of principal at December 31, 2018; however, these redemption prices generally decrease to 100% of the principal amount of the applicable notes over time as the notes approach maturity pursuant to a step-down schedule set forth in each of the indentures.
- Until a date specified in each indenture, the notes may be redeemed, in part (up to 35% of the principal amount outstanding) with the net cash proceeds from specified equity offerings at redemption prices set forth in each indenture, plus accrued and unpaid interest. As of December 31, 2018, this clause has expired for each of our notes except for the 2024 Notes, for which the specified redemption premium is 105.875%.

Other than the 2024 Notes, these notes are senior unsecured obligations of the Company's subsidiaries party to the applicable indentures governing such notes. These notes are issued by certain of the Company's subsidiaries and are guaranteed on a senior unsecured basis by the subsidiaries of Endo International plc that also guarantee the Credit Agreement, except for a de minimis amount of the 7.25% Senior Notes due 2022, which are issued by EHSI and guaranteed on a senior unsecured basis by the guarantors named in the Fifth Supplemental Indenture relating to such notes. The 2024 Notes are senior secured obligations of Endo International plc and its subsidiaries that are party to the indenture governing such notes. These notes are issued by certain of our subsidiaries and are guaranteed on a senior secured basis by Endo International plc and its subsidiaries that also guarantee our Credit Agreement.

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

April 2017 Refinancing

The Company and/or certain of its subsidiaries entered into the Credit Agreement and issued the 2024 Notes on April 27, 2017 (the April 2017 Refinancing). The Company used the net proceeds under the Term Loan Facility, together with the net proceeds of the 2024 Notes and cash on hand, to refinance certain of its prior indebtedness and to pay related fees and expenses.

In connection with the April 2017 Refinancing, we incurred new debt issuance costs of approximately $56.7 million, which were allocated among the new debt instruments as follows: (i) $41.3 million to the Term Loan Facility, (ii) $10.5 million to the Revolving Credit Facility and (iii) $4.9 million to the 2024 Notes. These costs, together with $10.1 million of the previously deferred debt issuance costs associated with our prior revolving credit facility, were deferred and are being amortized as interest expense over the terms of the respective instruments. The remaining $51.7 million of deferred debt issuance costs associated with our prior revolving and term loan facilities were charged to expense in the second quarter of 2017. These expenses were included in the Consolidated Statements of Operations as Loss on extinguishment of debt.

Maturities

The following table presents the maturities on our long-term debt for each of the five fiscal years subsequent to December 31, 2018 (in thousands):

	Maturities (1)
2019	$ 34,150
2020	$ 34,150
2021	$ 34,150
2022	$ 1,134,150
2023	$ 2,419,150

(1) As described above under the heading "Credit Facilities," certain amounts borrowed pursuant to the Credit Facilities will immediately mature if certain of our senior notes are not refinanced or repaid in full prior to the date that is 91 days prior to the respective stated maturity dates thereof. Accordingly, we may be required to repay or refinance senior notes with aggregate principal amounts of $1,100.0 million in 2021, despite such notes having stated maturities in 2022, and/or $750.0 million in 2022, despite such notes having stated maturities in 2023. The amounts in this maturities table do not reflect any such early payment; rather, they reflect stated maturity dates.

NOTE 15. COMMITMENTS AND CONTINGENCIES

Manufacturing, Supply and Other Service Agreements

Our subsidiaries contract with various third party manufacturers, suppliers and service providers to provide raw materials used in our subsidiaries' products and semi-finished and finished goods, as well as certain packaging, labeling services, customer service support, warehouse and distribution services. If, for any reason, we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products or services needed to conduct our business, it could have an adverse effect on our business, financial condition, results of operations and cash flows.

In addition to the manufacturing and supply agreements described above, we have agreements with various companies for clinical development services. Although we have no reason to believe that the parties to these agreements will not meet their obligations, failure by any of these third parties to honor their contractual obligations may have a material adverse effect on our business, financial condition, results of operations and cash flows.

Jubilant HollisterStier Laboratories LLC (JHS)

During the second quarter of 2016, we entered into a new agreement with JHS (the JHS Agreement). Pursuant to the JHS Agreement, JHS fills and lyophilizes the XIAFLEX® bulk drug substance, which is manufactured by the Company, 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 Company is required to purchase a specified percentage of its total forecasted volume of XIAFLEX® from JHS each year, unless JHS is unable to supply XIAFLEX® within the timeframe established under such forecasts. Amounts purchased pursuant to the JHS Agreement were $7.5 million, $5.6 million and $6.3 million for the years ended December 31, 2018, 2017 and 2016.

Milestones and Royalties

See Note 11. License and Collaboration Agreements for a description of future milestone and royalty commitments pursuant to our material acquisitions, license and collaboration agreements.

Legal Proceedings and Investigations

We and certain of our subsidiaries are involved in various claims, legal proceedings and internal and governmental investigations (collectively, proceedings) that arise from time to time in the ordinary course of our business, including, among others, those relating to product liability, intellectual property, regulatory compliance, consumer protection and commercial matters. While we cannot predict the outcome of these proceedings and we intend to vigorously prosecute or defend our position as appropriate, there can be no assurance that we will be successful or obtain any requested relief, and an adverse outcome in any of these proceedings could have a material adverse effect on our current and future financial position, results of operations and cash flows. Matters that are not being disclosed herein are, in the opinion of our management, immaterial both individually and in the aggregate with respect to our financial position, results of operations and cash flows. If and when such matters, in the opinion of our management, become material, either individually or in the aggregate, we will disclose them.

We believe that certain settlements and judgments, as well as legal defense costs, relating to certain product liability or other matters are or may be covered in whole or in part under our insurance policies with a number of insurance carriers. In certain circumstances, insurance carriers reserve their rights to contest or deny coverage. We intend to contest vigorously any and all disputes with our insurance carriers and to enforce our rights under the terms of our insurance policies. Accordingly, we will record receivables with respect to amounts due under these policies only when the resolution of any dispute has been reached and realization of the potential claim for recovery is considered probable. Amounts recovered under our insurance policies could be materially less than the stated coverage limits and may not be adequate to cover damages and/or costs relating to claims. In addition, there is no guarantee that insurers will pay claims or that coverage will otherwise be available.

As of December 31, 2018, our accrual for loss contingencies totaled $905.1 million, of which $748.6 million relates to our liability accrual for vaginal mesh cases and other mesh-related matters. During the fourth quarter of 2017, the Company recorded a total increase to its liability accrual of approximately $200 million related to testosterone-related product liability matters and LIDODERM®-related antitrust matters. The accrual for LIDODERM®-related matters includes an estimated loss for, among other matters, settlement of all remaining claims filed against EPI in multidistrict litigation (MDL) No. 2521 (defined below), which matters are further discussed below under the heading “Other Antitrust Matters.” The testosterone-related accrual includes an estimated loss for, among other matters, all testosterone-related product liability cases filed in MDL No. 2545 (defined below) and in other courts. These cases are further discussed below under the heading “Product Liability and Related Matters.” Although we believe there is a reasonable possibility that a loss in excess of the amount recognized exists, we are unable to estimate the possible loss or range of loss in excess of the amount recognized at this time.

Product Liability and Related Matters

We and certain of our subsidiaries have been named as defendants in numerous lawsuits in various U.S. federal and state courts, as well as in Canada and other countries, alleging personal injury resulting from the use of certain products of our subsidiaries. These and other related matters are described below in more detail.

Vaginal Mesh. Since 2008, we and certain of our subsidiaries, including American Medical Systems Holdings, Inc. (subsequently converted to Astora Women's Health Holding LLC and merged into Astora Women's Health LLC and referred to herein as AMS) and/or Astora, have been named as defendants in multiple lawsuits in various state and federal courts in the U.S. (including a federal MDL pending in the U.S. District Court for the Southern District of West Virginia (MDL No. 2325)), and in Canada and other countries, alleging personal injury resulting from the use of transvaginal surgical mesh products designed to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). In January 2018, a representative proceeding (class action) was filed in the Federal Court of Australia against American Medical Systems, LLC. In the various class action and individual complaints, plaintiffs claim a variety of personal injuries, including chronic pain, incontinence, inability to control bowel function and permanent deformities, and seek compensatory and punitive damages, where available.

We and certain plaintiffs' counsel representing mesh-related product liability claimants have entered into various Master Settlement Agreements (MSAs) and other agreements to resolve up to approximately 71,000 filed and unfiled mesh claims handled or controlled by the participating counsel. These MSAs and other agreements were entered into at various times between June 2013 and the present, were solely by way of compromise and settlement and were not in any way an admission of liability or fault by us or any of our subsidiaries.

All MSAs are subject to a process that includes guidelines and procedures for administering the settlements and the release of funds. In certain cases, the MSAs provide for the creation of QSFs into which funds may be deposited pursuant to certain schedules set forth in those agreements. All MSAs have participation requirements regarding the claims represented by each law firm party to the MSA. In addition, one agreement gives us a unilateral right of approval regarding which claims may be eligible to participate under that settlement. To the extent fewer claims than are authorized under an agreement participate, the total settlement payment under that agreement will be reduced by an agreed-upon amount for each such non-participating claim. Funds deposited in QSFs are considered restricted cash and/or restricted cash equivalents.

Distribution of funds to any individual claimant is conditioned upon the receipt of documentation substantiating the validity of the claim, a full release and dismissal of the entire action or claim as to all AMS parties and affiliates. Prior to receiving funds, an individual claimant is required to represent and warrant that liens, assignment rights or other claims identified in the claims administration process have been or will be satisfied by the individual claimant. Confidentiality provisions apply to the amount of settlement awards to participating claimants, the claims evaluation process and procedures used in conjunction with award distributions, and the negotiations leading to the settlements.

In June 2017, the MDL court entered a case management order which, among other things, requires plaintiffs in newly-filed MDL cases to provide expert disclosures on specific causation within one hundred twenty (120) days of filing a claim (the Order). Under the Order, a plaintiff's failure to meet the foregoing deadline may be grounds for the entry of judgment against such plaintiff. In July 2017, a similar order was entered in Minnesota state court. In June 2018, at the request of the MDL court, the Judicial Panel on Multidistrict Litigation entered a minute order suspending the transfer of cases into the MDL. Subsequently, the MDL court issued a pretrial order discontinuing the direct filing of claims in MDL No. 2325. The MDL court also issued similar orders in other MDLs involving claims against other mesh manufacturers.

Although the Company believes it has appropriately estimated the probable total amount of loss associated with all matters as of the date of this report, fact and expert discovery is ongoing in certain cases that have not settled, and it is reasonably possible that further claims may be filed or asserted and that adjustments to our liability accrual may be required. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The following table presents the changes in the QSFs and mesh liability accrual balances during the year ended December 31, 2018 (in thousands):

	Qualified Settlement Funds	Mesh Liability Accrual
Balance as of January 1, 2018	$ 313,814	$ 1,087,172
Additional charges	—	34,000
Cash contributions to Qualified Settlement Funds	336,648	—
Cash distributions to settle disputes from Qualified Settlement Funds	(353,032)	(353,032)
Cash distributions to settle disputes	—	(25,222)
Other (1)	2,303	5,688
Balance as of December 31, 2018	$ 299,733	$ 748,606

(1) Amounts deposited in the QSFs may earn interest, which is generally used to pay administrative costs of the fund and is reflected in the table above as an increase to the QSF and Mesh Liability Accrual balances. Any interest remaining after all claims have been paid will generally be distributed to the claimants who participated in that settlement. The $5.7 million in the table above also includes a second quarter 2018 reclassification adjustment of $4.4 million for accrued interest amounts previously recorded in Accounts payable and accrued expenses in the Consolidated Balance Sheets.

While the timing of the resolution of certain of the matters included in this mesh liability accrual remains uncertain, as of December 31, 2018, the entire liability accrual amount is classified in the Current portion of the legal settlement accrual in the Consolidated Balance Sheets. Charges related to vaginal mesh liability and associated legal fees and other expenses for all periods presented are reported in Discontinued operations, net of tax in our Consolidated Statements of Operations.

To date, the Company has made total mesh liability payments of approximately $3.3 billion, $299.7 million of which remains in the QSFs as of December 31, 2018. We currently expect to fund into the QSFs the remaining payments under all settlement agreements during 2019. As the funds are disbursed out of the QSFs from time to time, the liability accrual will be reduced accordingly with a corresponding reduction to restricted cash and cash equivalents. In addition, we may pay cash distributions to settle disputes separate from the QSFs, which will also decrease the liability accrual and decrease cash and cash equivalents.

We were contacted in October 2012 regarding a civil investigation initiated by various state attorneys general into mesh products, including transvaginal surgical mesh products designed to treat POP and SUI. In November 2013, we received a subpoena relating to this investigation from the state of California, and we have subsequently received additional subpoenas from California and other states. We are cooperating with these investigations.

We will continue to vigorously defend any unresolved claims and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any additional losses that could be incurred.

Testosterone. Various manufacturers of prescription medications containing testosterone, including our subsidiaries Endo Pharmaceuticals Inc. (EPI) and Auxilium Pharmaceuticals, Inc. (subsequently converted to Auxilium Pharmaceuticals, LLC and hereinafter referred to as Auxilium), have been named as defendants in multiple lawsuits alleging personal injury resulting from the use of such medications, including FORTESTA® Gel, DELATESTRYL®, TESTIM®, TESTOPEL®, AVEED® and STRIANT®. Plaintiffs in these suits generally allege various personal injuries, including pulmonary embolism, stroke or other vascular and/or cardiac injuries, and seek compensatory and/or punitive damages, where available.

As of February 21, 2019, we were aware of approximately 1,105 testosterone cases (some of which may have been filed on behalf of multiple plaintiffs) pending against one or more of our subsidiaries in federal or state court. Most of these cases have been coordinated in a federal MDL pending in the U.S. District Court for the Northern District of Illinois (MDL No. 2545). An MDL trial against Auxilium involving TESTIM® took place in November 2017 and resulted in a defense verdict. A trial against Auxilium involving TESTIM® was scheduled for January 2018 in the Philadelphia Court of Common Pleas but resolved prior to trial.

In June 2018, counsel for plaintiffs, on the one hand, and Auxilium and EPI, on the other, executed an MSA allowing for the resolution of all known testosterone replacement therapy product liability claims against our subsidiaries. The MSA was solely by way of compromise and settlement and was not in any way an admission of fault by us or any of our subsidiaries.

The MSA is subject to a process that includes guidelines and procedures for administering the settlement and the release of funds. Among other things, the MSA provides for the creation of a QSF into which the settlement funds will be deposited, establishes participation requirements and allows for a reduction of the total settlement payment in the event the participation threshold is not met. Distribution of funds to any individual claimant is conditioned upon the receipt of documentation substantiating product use and injury as determined by a third-party special master, the dismissal of any lawsuit and the release of the claim as to us and all affiliates. Prior to receiving funds, an individual claimant must represent and warrant that liens, assignment rights or other claims identified in the claims administration process have been or will be satisfied by the individual claimant. Confidentiality provisions apply to the settlement funds, amounts allocated to individual claimants and other terms of the agreement.

Although the Company believes it has appropriately estimated the probable total amount of loss associated with testosterone-related product liability matters as of the date of this report, it is reasonably possible that further claims may be filed or asserted and that adjustments to our liability accrual may be required. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The MDL also included a lawsuit filed in November 2014 in the U.S. District for the Northern District of Illinois against EPI, Auxilium and various other manufacturers of testosterone products on behalf of a proposed class of health insurance companies and other third party payers that claim to have paid for certain testosterone products. This lawsuit is not part of the settlement described above. After a series of motions to dismiss, plaintiff filed a third amended complaint in April 2016, asserting civil claims for alleged violations of the Racketeer Influenced and Corrupt Organizations Act and negligent misrepresentation based on defendants' marketing of certain testosterone products. The court denied a motion to dismiss this complaint in August 2016. In July 2018, the court denied plaintiff's motion for class certification. In February 2019, the court granted defendants' motion for summary judgment.

We will continue to vigorously defend any unresolved claims and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any additional losses that could be incurred.

Opioid-Related Matters

Since 2014, multiple U.S. states, counties, other governmental persons or entities and private plaintiffs have filed suit against us and/or certain of our subsidiaries, including Endo Health Solutions Inc. (EHSI), EPI, Par Pharmaceutical, Inc. (PPI), Par Pharmaceutical Companies, Inc., Vintage Pharmaceuticals, LLC, Generics Bidco I, LLC and DAVA Pharmaceuticals, LLC, as well as various other manufacturers, distributors and/or others, asserting claims relating to defendants' alleged sales, marketing and/or distribution practices with respect to prescription opioid medications, including certain of our products. As of February 21, 2019, the cases of which we were aware include, but are not limited to, approximately 12 cases filed by or on behalf of states; approximately 1,711 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 121 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers and approximately 56 cases filed by individuals. Certain of the cases have been filed as putative class actions. In addition to the litigation in the U.S., in August 2018, an action against Paladin Labs, EPI, the Company and various other manufacturers and distributors was commenced in British Columbia on behalf of all federal, provincial and territorial governments and agencies in Canada that paid healthcare, pharmaceutical and treatment costs related to opioids.

Many of the U.S. cases have been coordinated in a federal MDL pending in the U.S. District Court for the Northern District of Ohio (MDL No. 2804). In March 2018, the U.S. Department of Justice (DOJ) filed a statement of interest in the case, and in April 2018 it filed a motion to participate in settlement discussions as a friend of the court, which the MDL court has granted. The MDL court has issued a series of case management orders permitting motions to dismiss addressing threshold legal issues in certain cases, setting a trial date in October 2019 for the claims of two Ohio counties, allowing certain discovery and establishing certain other deadlines and procedures, among other things.

Other cases remain pending in various state courts. In some jurisdictions, such as Connecticut, Illinois, New York, Pennsylvania, South Carolina and Texas, certain state court cases have been transferred to a single court within their respective state court systems for coordinated pretrial proceedings. The state cases are generally at the pleading and/or discovery stage with certain of these cases scheduled for trial beginning in 2020.

The complaints in the cases assert a variety of claims including, but not limited to, claims for alleged violations of public nuisance, consumer protection, unfair trade practices, racketeering, Medicaid fraud and/or drug dealer liability statutes and/or common law claims for public nuisance, fraud/misrepresentation, strict liability, negligence and/or unjust enrichment. The claims are generally based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid medications and/or an alleged failure to take adequate steps to prevent abuse and diversion. Plaintiffs generally seek declaratory and/or injunctive relief; compensatory, punitive and/or treble damages; restitution, disgorgement, civil penalties, abatement, attorneys' fees, costs and/or other relief.

We will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred.

In addition to the lawsuits described above, the Company and/or its subsidiaries have received certain subpoenas, civil investigative demands (CIDs) and informal requests for information concerning the sale, marketing and/or distribution of prescription opioid medications, including the following:

Various state attorneys general have served subpoenas and/or CIDs on EHSI and/or EPI. We are cooperating with these investigations.

In January 2018, our subsidiary EPI received a federal grand jury subpoena from the U.S. District Court for the Southern District of Florida in connection with an investigation being conducted by the U.S. Attorney's Office for the Southern District of Florida in conjunction with the FDA. The subpoena seeks information related to OPANA® ER and other oxymorphone products. EPI is cooperating with the investigation.

Similar investigations may be brought by others or the foregoing matters may be expanded or result in litigation. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred.

Generic Drug Pricing Matters

In December 2014, we received a grand jury subpoena from the Antitrust Division of the DOJ issued by the U.S. District Court for the Eastern District of Pennsylvania addressed to Par Pharmaceuticals. The subpoena requested documents and information focused primarily on product and pricing information relating to the authorized generic version of Lanoxin (digoxin) oral tablets and generic doxycycline products, and on communications with competitors and others regarding those products. We are cooperating with the investigation.

In May 2018, we and our subsidiary Par Pharmaceutical Companies, Inc. each received a CID from the U.S. Department of Justice in relation to a False Claims Act investigation concerning whether generic pharmaceutical manufacturers engaged in price-fixing and market allocation agreements, paid illegal remuneration and caused the submission of false claims. We are cooperating with the investigation.

Similar investigations may be brought by others or the foregoing matters may be expanded or result in litigation. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred.

Since November 2016, various private plaintiffs and state attorneys general have filed cases against our subsidiary PPI and/or, in some instances, the Company, Generics Bidco I, LLC, DAVA Pharmaceuticals, LLC and/or Par Pharmaceutical Companies, Inc., as well as other pharmaceutical manufacturers and, in some instances, other corporate and/or individual defendants, alleging price-fixing and other anticompetitive conduct with respect to generic pharmaceutical products. These cases, which include proposed class actions filed on behalf of direct purchasers, end-payers and indirect purchaser resellers, have been consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Eastern District of Pennsylvania under the caption *In re Generic Pharmaceuticals Pricing Antitrust Litigation* (MDL No. 2724).

The various complaints generally assert claims under federal and/or state antitrust law, state consumer protection statutes and/or state common law, and seek damages, treble damages, civil penalties, disgorgement, declaratory and injunctive relief, costs and attorneys' fees. Some claims are based on alleged product-specific conspiracies. With respect to our subsidiaries, the allegations in the various complaints focus on amitriptyline, baclofen, digoxin, divalproex ER, doxycycline hyclate, doxycycline monohydrate, nystatin, propranolol and/or zoledronic acid. Other claims allege broader, multiple-product conspiracies involving various combinations of these and/or other products. Under these overarching conspiracy theories, plaintiffs seek to hold all alleged participants in a particular conspiracy jointly and severally liable for all harms caused by the alleged conspiracy, not just harms related to the products manufactured and/or sold by a particular defendant.

In October 2018, the MDL court denied defendants' motions to dismiss federal antitrust claims relating to digoxin, divalproex ER and doxycycline hyclate, among other products. In February 2019, the MDL dismissed certain state law claims but allowed others to proceed. In February 2019, the defendants moved to dismiss plaintiffs' overarching conspiracy claims. The MDL court has also allowed certain discovery.

We will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred.

Other Antitrust Matters

Beginning in November 2013, multiple direct and indirect purchasers of LIDODERM® filed a number of cases against our subsidiary EPI and other pharmaceutical companies generally alleging that they had entered into an anticompetitive agreement to restrain trade through the settlement of patent infringement litigation concerning U.S. Patent No. 5,827,529 (the '529 patent) and other patents. The complaints asserted claims under Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1, 2), and/or various state antitrust and consumer protection statutes, as well as common law claims, and generally sought damages, treble damages, disgorgement of profits, restitution, injunctive relief and attorneys' fees. The cases were consolidated and/or coordinated in April 2014 in a federal MDL in the U.S. District Court for the Northern District of California (MDL No. 2521). The MDL court certified classes of direct and indirect purchasers in February 2017. EPI settled with certain opt-out retailer plaintiffs in October 2017. In September 2018, the court approved EPI's settlement with the class plaintiffs and entered judgment dismissing the class cases with prejudice. In connection with the settlements, several indirect purchasers which previously had opted out were permitted to rejoin the class. The class settlement agreements provide for aggregate payments of approximately $100 million. As of February 21, 2019, EPI had paid approximately $70 million of this total, including approximately $60 million in 2018 and approximately $10 million in February 2019.

Beginning in June 2014, multiple direct and indirect purchasers of OPANA® ER filed cases against our subsidiaries EHSI and EPI and other pharmaceutical companies, including Impax Laboratories, LLC (formerly Impax Laboratories, Inc. and referred to herein as Impax) and Penwest Pharmaceuticals Co., which our subsidiary EPI had acquired. Some cases were filed on behalf of putative classes of direct and indirect purchasers, while others were filed on behalf of individual retailers or health care benefit plans. All cases have been consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Northern District of Illinois (MDL No. 2580). Plaintiffs generally allege that an agreement reached by EPI and Impax to settle patent infringement litigation concerning multiple patents pertaining to OPANA® ER and EPI's introduction of reformulated OPANA® ER violated antitrust laws. The complaints assert claims under Sections 1 and 2 of the Sherman Act, various state antitrust and consumer protection statutes and/or state common law. Plaintiffs generally seek damages, treble damages, disgorgement of profits, restitution, injunctive relief and attorneys' fees. In February 2016, the MDL court issued orders (i) denying defendants' motion to dismiss the claims of the direct purchasers, (ii) denying in part and granting in part defendants' motion to dismiss the claims of the indirect purchasers, but giving them permission to file amended complaints and (iii) granting defendants' motion to dismiss the complaints filed by certain retailers, but giving them permission to file amended complaints. In response to the MDL court's orders, the indirect purchasers filed an amended complaint to which the defendants filed a renewed motion to dismiss certain claims, and certain retailers also filed amended complaints. The court has dismissed the indirect purchaser unjust enrichment claims arising under the laws of the states of California, Rhode Island and Illinois. The cases are currently in discovery. We will continue to vigorously defend these matters and to explore other options as appropriate in our best interests.

Beginning in February 2009, the FTC and certain private plaintiffs, including distributors and retailers, filed suit against our subsidiary Par Pharmaceutical Companies, Inc. (since June 2016, Endo Generics Holdings, Inc., and referred to in this Commitments and Contingencies note as EGHI) and other pharmaceutical companies alleging violations of antitrust law arising out of their settlement of certain patent litigation concerning the generic version of AndroGel®. Generally, the complaints seek damages, treble damages, equitable relief and attorneys' fees and costs. The cases have been consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Northern District of Georgia (MDL No. 2084). In September 2012, the MDL court granted summary judgment to defendants on plaintiffs' claims of sham litigation. In May 2016, plaintiffs representing a putative class of indirect purchasers voluntarily dismissed their claims with prejudice. In February 2017, the FTC voluntarily dismissed its claims against EGHI with prejudice. Claims by certain alleged direct purchasers or their assignees are still pending against EGHI and other defendants. In June 2018, the MDL court granted in part and denied in part various summary judgment and evidentiary motions filed by defendants. In particular, the court rejected two of direct purchasers' three causation theories, rejected damages claims related to AndroGel® 1.62% and granted in part a motion seeking to exclude part of plaintiffs' proposed manufacturing expert's opinions. The motions were denied in all other respects, and the court denied a motion for reconsideration, or in the alternative leave to file an interlocutory appeal, in October 2018. In July 2018, the district court denied certain plaintiffs' motion for certification of a direct purchaser class. We will continue to vigorously defend these matters and to explore other options as appropriate in our best interests.

Beginning in May 2018, multiple alleged direct and indirect purchasers filed complaints in the U.S. District Court for the Southern District of New York against PPI, EPI and/or us, as well as others, alleging a conspiracy to delay generic competition and monopolize the market for Exforge® (amlodipine/valsartan) and its generic equivalents. Some cases were filed on behalf of putative classes of direct and indirect purchasers; others were filed on behalf of individual retailers. The plaintiffs generally assert claims under Sections 1 and 2 of the Sherman Act, various state antitrust and consumer protection statutes and state common law and seek damages, treble damages, equitable relief and attorneys' fees and costs. In September 2018, the putative class plaintiffs stipulated to the dismissal without prejudice of their claims against EPI and us, and the retailer plaintiffs did the same in November and December 2018. PPI filed a partial motion to dismiss certain claims in September 2018, which has not yet been ruled upon. We intend to vigorously defend these matters and to explore other options as appropriate in our best interests.

In November 2014, EPI received a CID from Florida's Office of the Attorney General seeking documents and other information concerning EPI's agreement with Actavis settling the LIDODERM® patent litigation, as well as information concerning marketing and sales of LIDODERM®. EPI and/or EHSI later received similar CIDs from other states. A CID from Alaska's Office of the Attorney General in February 2015 included requests for documents and information concerning agreements with Actavis and Impax settling the OPANA® ER patent litigation. We are cooperating with these investigations.

In February 2015, EGHI and affiliates received a CID from the Office of the Attorney General for the state of Alaska seeking production of certain documents and information regarding EGHI's settlement of the AndroGel® patent litigation as well as documents produced in the aforementioned litigation filed by the FTC. We are cooperating with this investigation.

Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any additional losses that could be incurred.

Securities Litigation

In May 2016, a putative class action entitled *Craig Friedman v. Endo International plc, Rajiv Kanishka Liyanaarchchie de Silva and Suketu P. Upadhyay* was filed in the U.S. District Court for the Southern District of New York by an individual shareholder on behalf of himself and all similarly situated shareholders. In August 2016, the court appointed Steamfitters' Industry Pension Fund and Steamfitters' Industry Security Benefit Fund as lead plaintiffs in the action. In October 2016, plaintiffs filed a second amended complaint that, among other things, added Paul Campanelli as a defendant, and we filed a motion to dismiss. In response, and without resolving the motion, the court permitted lead plaintiffs to file a third amended complaint. The amended complaint alleged violations of Sections 10(b) and 20(a) of the Exchange Act based on the Company's revision of its 2016 earnings guidance and certain disclosures about its generics business, the integration of Par Pharmaceutical Holdings, Inc. and its subsidiaries, certain other alleged business issues and the receipt of a CID from the U.S. Attorney's Office for the Southern District of New York regarding contracts with pharmacy benefit managers concerning FROVA®. Lead plaintiffs sought class certification, damages in an unspecified amount and attorneys' fees and costs. We filed a motion to dismiss the third amended complaint in December 2016. In January 2018, the court granted our motion and dismissed the case with prejudice. In February 2018, lead plaintiffs filed a motion for relief from the judgment and leave to file a fourth amended complaint; the court denied this motion in April 2018. Lead plaintiffs appealed to the U.S. Court of Appeals for the Second Circuit; that appeal is still pending.

In February 2017, a putative class action entitled *Public Employees' Retirement System of Mississippi v. Endo International plc* was filed in the Court of Common Pleas of Chester County, Pennsylvania by an institutional purchaser of shares in our June 2, 2015 public offering, on behalf of itself and all similarly situated purchasers. The lawsuit alleges violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 against Endo, certain of its current and former directors and officers, and the underwriters who participated in the offering, based on certain disclosures about Endo's generics business. In March 2017, defendants removed the case to the U.S. District Court for the Eastern District of Pennsylvania. In August 2017, the court remanded the case back to the Chester County Court of Common Pleas. In October 2017, plaintiff filed an amended complaint. In December 2017, defendants filed preliminary objections to the amended complaint. The court denied those preliminary objections in April 2018. The case is currently in discovery. Plaintiff filed its motion for class certification in July 2018.

In April 2017, a putative class action entitled *Phaedra A. Makris v. Endo International plc, Rajiv Kanishka Liyanaarchchie de Silva and Suketu P. Upadhyay* was filed in the Superior Court of Justice in Ontario, Canada by an individual shareholder on behalf of herself and similarly-situated Canadian-based investors who purchased Endo's securities between January 11 and May 5, 2016. The statement of claim generally seeks class certification, declaratory relief, damages, interest and costs based on alleged violations of the Ontario Securities Act. The statement of claim alleges negligent misrepresentations concerning the Company's revenues, 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 Company's U.S. generic pharmaceuticals business. In January 2019, plaintiff amended her statement of claim to add a claim on behalf of herself and similarly-situated Canadian investors who purchased Endo's securities between January 11, 2016 and June 8, 2017. This new claim is based on the Company's decision to remove reformulated OPANA® ER from the market.

In August 2017, a putative class action entitled *Bier v. Endo International plc, et al.* was filed in the U.S. District Court for the Eastern District of Pennsylvania by an individual shareholder on behalf of himself and all similarly situated shareholders. The original complaint alleged violations of Section 10(b) and 20(a) of the Exchange Act against Endo and four current and former directors and officers, based on the Company's decision to remove reformulated OPANA® ER from the market. In December 2017, the court appointed SEB Investment Management AB lead plaintiff in the action. In February 2018, the lead plaintiff filed an amended complaint, which added claims alleging violations of Sections 11 and 15 of the Securities Act in connection with the June 2015 offering. The amended complaint named the Company, EHSI and 20 current and former directors, officers and employees of Endo as defendants. In April 2018, the defendants moved to dismiss the amended complaint. In December 2018, the court dismissed the plaintiff's claims against four individual defendants, but otherwise denied the motion to dismiss.

In November 2017, a putative class action entitled *Pelletier v. Endo International plc, Rajiv Kanishka Liyanaarchchie De Silva, Suketu P. Upadhyay, and Paul V. Campanelli* was filed in the U.S. District Court for the Eastern District of Pennsylvania by an individual shareholder on behalf of himself and all similarly situated shareholders. The lawsuit alleges violations of Section 10(b) and 20(a) of the Exchange Act relating to the pricing of various generic pharmaceutical products. In June 2018, the court appointed *Park Employees' Annuity and Benefit Fund of Chicago* lead plaintiff in the action. In August 2018, the lead plaintiff filed an amended complaint. In September 2018, the defendants moved to dismiss the amended complaint. That motion remains pending.

We will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred.

VASOSTRICT® Related Matters

In July 2016, Fresenius Kabi USA, LLC (Fresenius) filed a complaint against Par Pharmaceutical Companies, Inc. and its affiliate Par Sterile Products, LLC (PSP) in the U.S. District Court for the District of New Jersey alleging that Par Pharmaceutical Companies, Inc. and its affiliate engaged in an anticompetitive scheme to exclude competition from the market for vasopressin solution for intravenous injection in view of Par Pharmaceutical Companies, Inc.'s VASOSTRICT® (vasopressin) product. The complaint alleges violations of Sections 1 and 2 of the Sherman Antitrust Act, as well as state antitrust and common law, based on assertions that Par Pharmaceutical Companies, Inc. and its affiliate entered into exclusive supply agreements with one or more active pharmaceutical ingredient (API) manufacturers and that, as a result, Fresenius has been unable to obtain vasopressin API in order to file an ANDA to obtain FDA approval for its own vasopressin product. Fresenius seeks actual, treble and punitive damages, attorneys' fees and costs and injunctive relief. In September 2016, Par Pharmaceutical Companies, Inc. and its affiliate filed a motion to dismiss, which the district court denied in February 2017. The case is currently in discovery.

In August 2017, our subsidiaries PPI and PSP filed a complaint for actual, exemplary and punitive damages, injunctive relief and other relief against QuVa Pharma, Inc. (QuVa), Stuart Hinchen, Peter Jenkins and Mike Rutkowski in the U.S. District Court for the District of New Jersey. The complaint alleges misappropriation in violation of the federal Defend Trade Secrets Act, New Jersey's Trade Secrets Act and New Jersey common law, as well as unfair competition, breach of contract, breach of fiduciary duty, breach of the duty of loyalty, tortious interference with contractual relations and breach of the duty of confidence in connection with VASOSTRICT®, a vasopressin-based cardiopulmonary drug. In October 2017, defendants answered the complaint and QuVa asserted counterclaims against PPI and PSP alleging unfair competition under New Jersey common law and seeking declaratory judgment of non-infringement as to five U.S. Patents assigned to PPI that are listed in FDA's Orange Book for VASOSTRICT®. The counterclaims seek actual, exemplary and punitive damages, injunctive relief and other relief. We filed a motion to dismiss the unfair competition counterclaim in November 2017. Also in November 2017, we filed a motion for preliminary injunction seeking various forms of relief. In January 2018, we filed a first amended complaint adding four former employees and one consultant of PSP as defendants and numerous causes of action against some or all of those individuals, including misappropriation under the federal Defend Trade Secrets Act, New Jersey's Trade Secrets Act and New Jersey common law, as well as breach of contract, breach of the duty of loyalty and breach of the duty of confidence. In March 2018, the court granted in part our motion for preliminary injunction and enjoined QuVa from marketing and releasing its planned vasopressin product through the conclusion of trial. We subsequently deposited a bond to the court's interest-bearing account to secure the preliminary injunction. Defendants filed a motion asking the court to reconsider the bond amount, which the court denied. Also in March 2018, QuVa and seven of the individual defendants filed a motion to dismiss the New Jersey common law claims, four of the individual defendants filed a motion to dismiss for lack of personal jurisdiction and one of the individuals filed a motion to dismiss the breach of contract claim. In April 2018, another individual defendant filed a motion to dismiss asserting numerous arguments, including lack of personal jurisdiction, improper venue and choice of law. Discovery began in May 2018. Also in May 2018, defendants filed a notice of appeal to the Third Circuit Court of Appeal indicating intent to appeal the court's preliminary injunction. In October 2018, defendants filed their opening appellate brief, in December 2018, we filed our response brief and in January 2019, defendants filed their reply brief. Also in January 2019, the court denied all four of defendants' pending motions to dismiss, as well as our pending motion to dismiss, which the court found was moot in light of the first amended complaint. In February 2019, the defendants filed their answers and affirmative defenses, and certain defendants also filed counterclaims.

In October 2017, Endo Par Innovation Company, LLC (EPIC) and PSP filed a complaint in the United States District Court for the District of Columbia challenging the legality of the FDA's *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (January 2017) with respect to the listing of vasopressin in Category 1 of the *Interim Policy*. The complaint contends that the *Interim Policy* is unlawful because it is inconsistent with the Federal Food, Drug, and Cosmetic Act, including, but not limited to, Section 503B of that Act. The complaint seeks (i) a declaration that FDA's *Interim Policy* and its listing of vasopressin in Category 1 of the *Interim Policy* are unlawful, and (ii) an order enjoining and vacating the *Interim Policy* and the FDA's listing of vasopressin in Category 1 of the *Interim Policy*. In January 2018, EPIC and PSP agreed to a temporary 60-day stay of the litigation in light of the FDA's announcement that forthcoming guidance would address the concerns set forth in the Company's complaint. In March 2018, the FDA released new draft guidance for industry entitled "Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Shortly thereafter, the parties agreed to extend the temporary stay for an additional 180 days. In August 2018, before the 180-day stay period expired, Athenex Pharma Solutions, LLC and Athenex Pharmaceutical Division, LLC announced they had commenced bulk compounding of vasopressin, and moved to intervene in EPIC and PSP's case against the FDA. Later that month, EPIC and PSP invoked their ability to terminate the stay and filed a Motion for Preliminary Injunction. Before responding to the Motion for Preliminary Injunction, the FDA issued a notice containing a proposed finding that there is no clinical need to bulk compound vasopressin under Section 503B in August 2018. In September 2018, the FDA advised EPIC and PSP that it would agree to use its best efforts to finalize the vasopressin clinical need rulemaking by December 31, 2018, if the case were again stayed. EPIC and PSP agreed to the requested stay. In December 2018, the appropriations act that had been funding the Department of Justice and components of the FDA expired, resulting in a lapse of appropriations; therefore, the FDA moved the court for a further stay of the case until appropriations were restored. The court granted the motion in January 2019, ordering the FDA to file a notification with the court within three business days of Department of Justice operations resuming. After government appropriations were restored, the FDA advised that it would use its best efforts to finalize the vasopressin clinical need determination by March 15, 2019. Based on that commitment, EPIC and PSP agreed not to oppose the FDA's request to stay the case again until the earliest of March 15, 2019, the publication of a final clinical need determination for vasopressin or a substantial change in circumstances necessitating a decision on EPIC and PSP's Motion for Preliminary Injunction. EPIC and PSP cannot currently be certain whether the FDA will request a further stay of the litigation, of the date on which the FDA will finalize its clinical need determination or of the date on which the litigation will be resolved.

In August 2018, Athenex filed a declaratory judgment action in the U.S. District Court for the Western District of New York, a case styled *Athenex v. Par*, alleging non-infringement and/or invalidity of the patents the Company has listed in the Orange Book in view of VASOSTRICT®. The Company moved to dismiss Athenex's case on multiple grounds in October 2018, which motion was opposed by Athenex in December 2018. The Company responded to this opposition in December 2018. This motion has not yet been decided.

In April 2018, PSP and PPI received a notice letter from Eagle Pharmaceuticals, Inc. (Eagle) advising of the filing by such company of an ANDA for a generic version of VASOSTRICT® (vasopressin IV solution (infusion)) 20 units/ml. In May 2018, PSP and PPI received a second notice letter from Eagle advising of the same filing, but adding an additional patent. The Paragraph IV notices refer to U.S. Patent Nos. 9,375,478; 9,687,526; 9,744,209; 9,744,239; 9,750,785; and 9,937,223, which variously cover either vasopressin-containing pharmaceutical compositions or methods of using a vasopressin-containing dosage form to increase blood pressure in humans. In May 2018, PPI, PSP and EPIC filed a lawsuit against Eagle in the United States District Court for the District of Delaware within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. In August 2018, Eagle filed an answer and a counterclaim for non-infringement and invalidity of asserted patents. A claim construction hearing is scheduled for May 2019, with a bench trial scheduled for May 2020.

In September 2018, PSP and PPI received a notice letter from Sandoz Inc. (Sandoz) advising of the filing by such company of an ANDA for a generic version of VASOSTRICT® (vasopressin IV solution (infusion)) 200 units/10 ml. In October 2018, PPI, PSP and EPIC filed a lawsuit against Sandoz in the United States District Court for the District of New Jersey within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. In October 2018, PSP and PPI received an additional notice letter from Sandoz advising of the filing by such company of an ANDA for a generic version of the 20 units/1 ml presentation for VASOSTRICT®. In November 2018, the complaint was amended to add a claim for the additional notice letter, within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. The Company continues to vigorously defend its intellectual property.

In November 2018, PSP and PPI received a notice letter from Amphastar Pharmaceuticals, Inc. (Amphastar) advising of the filing by such company of an ANDA for a generic version of VASOSTRICT® (vasopressin IV solution (infusion)) 20 units/1 ml. In December 2018, PPI, PSP and EPIC filed a lawsuit against Amphastar in the U.S. District Court for the District of Delaware within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. The Company continues to vigorously defend its intellectual property.

The Company's legal reserves include, among other things, an estimated accrual for certain VASOSTRICT®-related matters. We will continue to vigorously defend or prosecute the foregoing matters as appropriate, to protect our intellectual property rights, to pursue all available legal and regulatory avenues and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any additional losses that could be incurred.

Paragraph IV Certifications on OPANA® ER

In August 2014 and October 2014, the U.S. Patent Office issued U.S. Patent Nos. 8,808,737 (the '737 patent) and 8,871,779 (the '779 patent) respectively, which cover a method of using OPANA® ER and a highly pure version of the API of OPANA® ER. In November 2014, EPI filed lawsuits against Teva, ThoRx, Actavis, Impax, Ranbaxy, Roxane, Amneal and Sandoz Inc. based on their ANDAs filed against both the INTAC® technology and non-INTAC® technology versions of OPANA® ER. Those lawsuits were filed in the U.S. District Court for the District of Delaware alleging infringement of these new patents, which expire in 2027 and 2029, respectively. On November 17, 2015, the District Court held the '737 patent invalid for claiming unpatentable subject matter. That patent has been dismissed from all suits and the suits administratively closed as to that patent, subject to appeal at the end of the case on the '779 patent. In July 2016, a three-day trial was held in the U.S. District Court for the District of Delaware against Teva and Amneal for infringement of the '779 patent. In October 2016, the District Court issued an opinion holding that the defendants infringed the claims of U.S. Patent No. 8,871,779. The opinion also held that the defendants had failed to show that the '779 patent was invalid. The District Court issued an Order enjoining the defendants from launching their generic products until the expiration of the '779 patent in November 2029. A trial for infringement of the '779 patent by Actavis was held in February 2017 in the same court (U.S. District Court for the District of Delaware) in front of the same judge. In August 2017, the District Court issued an opinion holding that Actavis infringed the claims of the '779 patent and that Actavis had failed to show that the '779 patent was invalid. Teva, Amneal and Actavis have appealed these holdings. We have appealed the holding that the '737 patent is invalid. A hearing on those appeals took place in December 2018.We are awaiting decisions on those appeals.

We will continue to vigorously defend or prosecute the foregoing matter as appropriate, to protect our intellectual property rights, to pursue all available legal and regulatory avenues and to explore other options as appropriate in our best interests in defense of our intellectual property, including enforcement of the product's intellectual property rights and approved labeling. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred.

Other Proceedings and Investigations

Proceedings similar to those described above may also be brought in the future. Additionally, we are involved in, or have been involved in, arbitrations or various other proceedings that arise from the normal course of our business. We cannot predict the timing or outcome of these other proceedings. Currently, neither we nor our subsidiaries are involved in any other proceedings that we expect to have a material effect on our business, financial condition, results of operations and cash flows.

Leases

We lease certain fixed assets under capital leases that expire through 2032. We lease automobiles, machinery and equipment and facilities under certain noncancelable operating leases that expire through 2028. These leases are renewable at our option.

On October 28, 2011, our subsidiary EPI entered into a lease agreement for a new Company headquarters in Malvern, Pennsylvania. The initial term of the lease is through 2024 and includes three renewal options, each for an additional 60-month period. This lease is accounted for as a direct financing arrangement whereby the Company recorded, over the construction period, the full cost of the asset in Property, plant and equipment, net. A corresponding liability was also recorded, net of leasehold improvements paid for by the Company, and is being amortized over the expected lease term through monthly rental payments using an effective interest method. At December 31, 2018, there was a liability of $33.8 million related to this arrangement, $4.9 million of which is included in Accounts payable and accrued expenses and $28.9 million of which is included in Other liabilities in the accompanying Consolidated Balance Sheet.

A summary of minimum future rental payments required under capital and operating leases as of December 31, 2018 are as follows (in thousands):

	Capital Leases (1) (2)	Operating Leases
2019	$ 6,884	$ 15,800
2020	6,819	14,519
2021	6,921	12,883
2022	7,072	12,454
2023	7,225	9,945
Thereafter	9,127	20,573
Total minimum lease payments	$ 44,048	$ 86,174
Less: Amount representing interest	4,084	
Total present value of minimum payments	$ 39,964	
Less: Current portion of such obligations	5,845	
Long-term capital lease obligations	$ 34,119	

(1) The direct financing arrangement is included under Capital Leases.

(2) We have entered into agreements to sublease certain properties. Most significantly, we sublease approximately 140,000 square feet of our Malvern, Pennsylvania headquarters and substantially all of our Chesterbrook, Pennsylvania facility. As of December 31, 2018, we expect to receive approximately $29.7 million in future minimum rental payments over the remaining terms of the Malvern and Chesterbrook subleases through 2024. Amounts included in this table have not been reduced by the minimum sublease rentals.

Expenses incurred under operating leases were approximately $18.7 million, $18.7 million and $22.2 million for the years ended December 31, 2018, 2017 and 2016, respectively.

NOTE 16. OTHER COMPREHENSIVE (LOSS) INCOME

Set forth below are the tax effects allocated to each component of Other comprehensive (loss) income for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018			2017			2016		
	Before-Tax Amount	Tax (Expense) Benefit	Net-of-Tax Amount	Before-Tax Amount	Tax Benefit (Expense)	Net-of-Tax Amount	Before-Tax Amount	Tax Benefit (Expense)	Net-of-Tax Amount
Net unrealized loss on securities:									
Unrealized loss arising during the period	$ —	$ —	$ —	$ (811)	$ 296	$ (515)	$ (1,588)	$ 674	$ (914)
Less: reclassification adjustments for (gain) loss realized in net loss	—	—	—	—	—	—	(6)	—	(6)
Net unrealized gains (losses) on securities	$ —	$ —	$ —	$ (811)	$ 296	$ (515)	$ (1,594)	$ 674	$ (920)
Net unrealized (loss) gain on foreign currency:									
Foreign currency translation (loss) gain arising during the period	(19,408)	—	(19,408)	31,202	—	31,202	18,267	13,462	31,729
Less: reclassification adjustments for loss realized in net loss	—	—	—	112,926	—	112,926	—	—	—
Foreign currency translation (loss) gain	$ (19,408)	$ —	$ (19,408)	$ 144,128	$ —	$ 144,128	$ 18,267	$ 13,462	$ 31,729
Other comprehensive (loss) income	$ (19,408)	$ —	$ (19,408)	$ 143,317	$ 296	$ 143,613	$ 16,673	$ 14,136	$ 30,809

Reclassification adjustments out of Other comprehensive (loss) income related to foreign currency translation were recorded upon the liquidation of Litha and Somar during 2017.

Substantially all of the Company's Accumulated other comprehensive loss at December 31, 2018 and December 31, 2017 consists of Foreign currency translation loss.

NOTE 17. SHAREHOLDERS' (DEFICIT) EQUITY

The Company 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

The Company early adopted ASU No. 2016-16, "*Intra-Entity Transfers of Assets Other Than Inventory*" (ASU 2016-16) on January 1, 2017, resulting in, among other effects, the elimination of previously recorded deferred charges that were established in 2016. Specifically, effective January 1, 2017, the Company eliminated $372.8 million of deferred charges and recorded a corresponding increase to its accumulated deficit.

As further discussed in Note 2. Summary of Significant Accounting Policies, the Company also adopted ASC 606 on January 1, 2018, resulting in a net decrease of $3.1 million to its accumulated deficit at January 1, 2018.

Share Repurchase Program

Pursuant to Article 11 of the Company's Articles of Association, the Company has broad shareholder authority to conduct ordinary share repurchases by way of redemptions. The Company'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 Company's Articles of Association, any ordinary shares redeemed shall be cancelled upon redemption.

The Board of Directors has approved a share buyback program (the 2015 Share Buyback Program) that authorizes the Company to redeem, in the aggregate, $2.5 billion of its outstanding ordinary shares. To date, the Company 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 18. SHARE-BASED COMPENSATION

As discussed in Note 3. Discontinued Operations and Divestitures, the operating results of the Company's Astora businesses are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. However, as share-based compensation is not material for these businesses, amounts in this Note 18. Share-based Compensation have not been adjusted to exclude the impact of these businesses.

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.

During the third quarter of 2017, the Company 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 Company'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 Company's outstanding Performance Share Units (PSUs) are measured upon the completion of three independent successive one-year performance targets, which are generally established for each performance period during the first quarter of that calendar year. The determination of the grant-date(s) underlying such PSUs depends in part on the date(s) on which each of the performance targets with respect to those PSUs are approved. Therefore, for certain PSUs, a single unit may give rise to multiple grant dates depending, in part, on the dates on which the respective performance targets are approved. As of December 31, 2018, there are 0.5 million PSUs outstanding, representing target amounts, for which a grant date has not yet been established. No fair value has been ascribed to these awards as no grant date has been established.

Beginning in 2017, long-term cash incentive (LTCI) awards were provided to certain employees. LTCI awards were designed to vest ratably, in equal amounts, over a three-year service period. Upon vesting, each vested LTCI unit would be settled in cash in an amount equal to the price of Endo's ordinary shares on the vest date. As of September 30, 2018, approximately 3.0 million unvested LTCI awards were outstanding for approximately 570 employees. The outstanding awards had a weighted average remaining requisite service period of 2.3 years. A corresponding liability of $14.9 million was recorded as of September 30, 2018 in Accounts payable and accrued expenses and Other liabilities in the Company's Condensed Consolidated Balance Sheets. On October 1, 2018, the Compensation Committee of the Board of Directors authorized the Company 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 18. 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 Statements of Operations subsequent to this modification, including adjustments related to actual or estimated forfeitures, are excluded from the determination of share-based compensation expense.

At December 31, 2018, approximately 5.5 million ordinary shares were reserved for future grants under the 2015 Plan. As of December 31, 2018, stock options, restricted stock awards, PSUs, RSUs and LTCI awards have been granted under the stock incentive plans.

Generally, the grant-date fair value of each award is recognized as expense over the requisite service period. However, expense recognition differs in the case of certain performance share units where the ultimate payout is performance-based. For these awards, at each reporting period, the Company 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 Statements of Operations for the years ended December 31, 2018, 2017 and 2016 (in thousands).

	2018	2017	2016
Selling, general and administrative expenses	$ 44,454	$ 38,292	$ 54,176
Research and development expenses	2,251	4,197	2,440
Cost of revenues	7,366	7,660	2,040
Discontinued operations (Note 3)	—	—	1,113
Total share-based compensation expense	$ 54,071	$ 50,149	$ 59,769

As of December 31, 2018, the total remaining unrecognized compensation cost related to all non-vested share-based compensation awards for which a grant date has been established as of December 31, 2018 amounted to $68.3 million.

Stock Options

From time to time, the Company 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 Company.

Employee stock options generally vest ratably, in equal amounts, over a three or four-year service period and expire ten years from the grant date. The fair value of option grants is estimated at the date of grant using the Black-Scholes option-pricing model. This model utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero as the Company 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 Company's share price over a period commensurate with the expected life of the share option as well as other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. We estimate the expected term of options granted based on our historical experience with our employees' exercise of stock options and other factors.

A summary of the activity for each of the years ended December 31, 2018, 2017 and 2016 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (1)
Outstanding as of January 1, 2016	2,768,567	$ 51.56		
Granted	2,578,105	$ 35.45		
Exercised	(62,589)	$ 31.19		
Forfeited	(858,556)	$ 52.27		
Expired	(100,318)	$ 60.71		
Outstanding as of December 31, 2016	4,325,209	$ 41.70		
Granted	5,288,675	$ 10.42		
Forfeited	(623,987)	$ 28.32		
Expired	(741,767)	$ 40.29		
Outstanding as of December 31, 2017	8,248,130	$ 22.79		
Granted	971,590	$ 7.55		
Exercised	(94,392)	$ 9.89		
Forfeited	(605,737)	$ 19.01		
Expired	(446,873)	$ 36.80		
Outstanding as of December 31, 2018	8,072,718	$ 20.62	7.12	$ —
Vested and expected to vest as of December 31, 2018	7,833,930	$ 20.86	7.08	$ —
Exercisable as of December 31, 2018	3,550,777	$ 28.07	6.00	$ —

(1) The intrinsic value of a stock option is the excess, if any, of the closing price of the Company's ordinary shares on the last trading day of the fiscal year over the exercise price. The aggregate intrinsic values presented in the table above represent sum of the intrinsic values of all corresponding stock options that are "in-the-money," if any.

The range of exercise prices for the above stock options outstanding at December 31, 2018 is from $7.55 to $89.68.

No options were exercised during the year ended December 31, 2017. The total intrinsic value of options exercised during the years ended December 31, 2018 and 2016 was $0.6 million and $1.3 million, respectively. No tax benefits from stock option exercises were realized during the years ended December 31, 2018, 2017 and 2016. The weighted average grant-date fair value of the stock options granted in the years ended December 31, 2018, 2017 and 2016 was $3.97, $4.73 and $11.46 per option, respectively, determined using the following average assumptions:

	2018	2017	2016
Expected term (years)	4.0	4.0	4.0
Risk-free interest rate	2.7%	1.7%	1.1%
Dividend yield	—	—	—
Expected volatility	63%	58%	43%

As of December 31, 2018, the weighted average remaining requisite service period of non-vested stock options was 1.7 years and the total remaining unrecognized compensation cost related to non-vested stock options amounted to $9.4 million.

Restricted Stock Units and Performance Share Units

For PSUs for which a grant date has not yet occurred, such as those described above, no fair value has been established and these awards are not reflected in any of the amounts in this "Restricted Stock Units and Performance Share Units" section.

From time to time, the Company 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 Company.

RSUs vest ratably, in equal amounts, over a three or four-year service period. PSUs vest in full after a three-year service period and are conditional upon the achievement of performance and/or market conditions established by the Compensation Committee of the Board of Directors.

PSUs awarded in 2018 and 2017 were based upon two discrete measures: relative total shareholder return (TSR) and a free cash flow performance metric. The free cash flow performance metric, which accounts for 50% of the PSU award upon issuance, is measured upon the completion of three independent successive one-year performance targets, which are generally established for each performance period during the first quarter of that calendar year. The remaining 50% of the PSU award is tied exclusively to relative TSR performance, which will be measured against the three-year TSR of a custom index of companies. The actual number of shares awarded is adjusted to between zero and 200% of the target award amount based upon achievement of certain goals. In addition to meeting the performance conditions, grant recipients are also generally subject to being employed by the Company until the conclusion of the three-year vesting period in order to receive the awards. TSR relative to peers is considered a market condition under applicable authoritative guidance, while the free cash flow measure is considered performance condition.

In 2016, PSU grants are tied to relative TSR performance, which will be measured against the three-year TSR of a custom index of companies, with maximum payout levels also based on absolute compounded annual growth rate (CAGR) share price objectives. Each award covered a three-year performance cycle. The actual number of shares awarded is adjusted to between zero and 300% of the target award amount based upon achievement of pre-determined relative TSR and CAGR share price goals. TSR relative to peers is considered a market condition under applicable authoritative guidance.

RSUs are valued based on the closing price of Endo's ordinary shares on the date of grant. PSUs with TSR conditions are valued using a Monte-Carlo variant valuation model, while those with adjusted free cash flow conditions are valued taking into consideration the probability of achieving the specified performance goal. The Monte-Carlo variant valuation model considered a variety of potential future share prices for Endo as well as our peer companies in a selected market index.

A summary of our non-vested RSUs and PSUs for the years ended December 31, 2018, 2017 and 2016 is presented below:

	Number of Shares	Aggregate Intrinsic Value (1)
Non-vested as of January 1, 2016	1,806,853	
Granted	1,582,429	
Forfeited	(975,994)	
Vested	(728,228)	
Non-vested as of December 31, 2016	1,685,060	
Granted	4,168,477	
Forfeited	(552,981)	
Vested	(575,883)	
Non-vested as of December 31, 2017	4,724,673	
Granted	5,609,561	
LTCI modification (2)	2,989,965	
Forfeited	(753,653)	
Vested	(1,551,074)	
Non-vested as of December 31, 2018	11,019,472	$ 80,442,146
Vested and expected to vest as of December 31, 2018	10,250,560	$ 74,829,088

(1) The aggregate intrinsic values of RSUs and PSUs presented in the table above are calculated by multiplying the closing price of the Company'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 Company's LTCI awards described above, modified LTCI awards are treated as RSUs for disclosure purposes; thus, the table above reflects an increase to the non-vested number of shares on the modification date.

As of December 31, 2018, the weighted average remaining requisite service period of the units presented in the table above was 1.9 years and the corresponding total remaining unrecognized compensation cost amounted to $54.2 million in the case of RSUs and LTCI awards and $4.7 million in the case of PSUs. The weighted average grant-date fair value of the units granted during the years ended December 31, 2018, 2017 and 2016 was $6.88, $11.42 and $43.52 per unit, respectively.

NOTE 19. OTHER INCOME, NET

The components of Other income, net for the years ended December 31, 2018, 2017 and 2016 are as follows (in thousands):

	2018	2017	2016
Net (gain) loss on sale of business and other assets	$ (45,155)	$ (13,809)	$ 3,192
Foreign currency (gain) loss, net	(3,762)	(2,801)	2,991
Net loss (gain) from our investments in the equity of other companies	3,444	898	(1,190)
Other miscellaneous, net	(6,480)	(1,311)	(5,331)
Other income, net	$ (51,953)	$ (17,023)	$ (338)

In 2018, Net (gain) loss on sale of business and other assets primarily relates to proceeds received from the 2018 sales of various ANDAs and of the Huntsville facilities, as further discussed in Note 4. Restructuring.

In 2017, Net (gain) loss on sale of business and other assets includes a $10.1 million gain resulting from the sale of Litha, as further described in Note 3. Discontinued Operations and Divestitures.

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

NOTE 20. INCOME TAXES

Tax Reform

The TCJA, which was signed into law on December 22, 2017, has resulted in significant changes to the U.S. corporate income tax system. In addition to the reduction of the U.S. statutory federal corporate income tax rate from 35% to 21% effective January 1, 2018, the TCJA contains a broad range of domestic and international provisions, many of which differ significantly from those contained in previous U.S. tax law. Although the rate of U.S. federal income tax was reduced prospectively, changes in tax rates and laws are accounted for in the period of enactment. Therefore, during the year ended December 31, 2017, we recorded a benefit of $36.2 million as our provisional estimate of the impact of the TCJA in accordance with Staff Accounting Bulletin (SAB) 118. This benefit, which is primarily related to remeasurement of deferred tax liabilities related to tax deductible goodwill, has been recorded in our Consolidated Statements of Operations as Income tax benefit. The Company has completed its accounting for the tax effects of the TCJA in accordance with SAB 118. There were no significant adjustments to the provisional amounts recorded.

Income (Loss) Before Income Taxes

Our operations are conducted through our various subsidiaries in numerous jurisdictions throughout the world. We have provided for income taxes based upon the tax laws and rates in the jurisdictions in which our operations are conducted.

The components of our Loss from continuing operations before income tax by geography for the years ended December 31, 2018, 2017 and 2016 are as follows (in thousands):

	2018	2017	2016
United States	$ (1,342,860)	$ (1,866,222)	$ (4,309,211)
International	404,028	383,218	385,355
Total (loss) income from continuing operations before income tax	$ (938,832)	$ (1,483,004)	$ (3,923,856)

Income tax from continuing operations consists of the following for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Current:			
U.S. Federal	$ 6,236	$ (86,478)	$ 18,369
U.S. State	2,864	(6,462)	9,501
International	8,278	(1,224)	22,851
Total current income tax	$ 17,378	$ (94,164)	$ 50,721
Deferred:			
U.S. Federal	$ 10,084	$ (124,682)	$ (661,484)
U.S. State	(778)	(3,225)	(239)
International	(3,749)	(28,222)	(83,619)
Total deferred income tax	$ 5,557	$ (156,129)	$ (745,342)
Excess tax benefits of stock compensation exercised	—	—	(5,463)
Total income tax	$ 22,935	$ (250,293)	$ (700,084)

Tax Rate

A reconciliation of income tax from continuing operations at the U.S. federal statutory income tax rate to the total income tax provision from continuing operations for the years ended December 31, 2018, 2017 and 2016 is as follows (in thousands):

	2018	2017	2016
Notional U.S. federal income tax provision at the statutory rate	$ (197,155)	$ (519,051)	$ (1,373,350)
State income tax, net of federal benefit	494	(11,473)	5,182
U.S. tax reform impact	5,664	(36,216)	—
Uncertain tax positions	46,317	58,120	(18,111)
Residual tax on non-U.S. net earnings	(638,724)	(1,350,811)	(301,666)
Effects of outside basis differences	—	—	(636,134)
Non-deductible goodwill impairment	109,189	60,808	926,881
Change in valuation allowance	752,008	1,648,836	762,604
Intra-entity transfers of assets	(63,335)	(53,509)	(92,859)
International Pharmaceuticals segment divestitures	—	(56,092)	—
Other	8,477	9,095	27,369
Income tax	$ 22,935	$ (250,293)	$ (700,084)

During the year ended December 31, 2018, the tax expense primarily related to the establishment of a valuation allowance against certain U.S. deferred tax assets. During the year ended December 31, 2017, the tax benefit primarily related to pre-tax losses incurred by certain U.S. subsidiaries. During the year ended December 31, 2016, the Company recorded a $636.1 million net tax benefit related to worthless stock deductions that are reflected as a component of benefits from outside basis differences.

Deferred Tax Assets and Liabilities

Deferred income taxes result from temporary differences between the amount of assets and liabilities recognized for financial reporting and tax purposes. The significant components of the net deferred income tax liability shown on the balance sheets as of December 31, 2018 and 2017 are as follows (in thousands):

	December 31, 2018	December 31, 2017
Deferred tax assets:		
Accrued expenses and customer allowances	$ 185,910	$ 299,142
Deferred interest expense	240,736	46,230
Fixed assets and intangible assets	604,385	484,313
Loss on capital assets	62,033	49,585
Net operating loss carryforward	8,751,544	7,183,651
Other	65,266	56,828
Research and development and other tax credit carryforwards	9,551	6,354
Total gross deferred income tax assets	$ 9,919,425	$ 8,126,103
Deferred tax liabilities:		
Other	$ (1,965)	$ (2,042)
Outside basis difference	(73,652)	(92,635)
Total gross deferred income tax liabilities	$ (75,617)	$ (94,677)
Valuation allowance	(9,877,617)	(8,062,975)
Net deferred income tax liability	$ (33,809)	$ (31,549)

At December 31, 2018, the Company had the following significant deferred tax assets for net operating and capital loss carryforwards, net of unrecognized tax benefits (in thousands):

Jurisdiction	Amount	Begin to Expire
Ireland	$ 13,254	indefinite
Luxembourg	$ 8,378,742	2034
United States:		
Federal-ordinary losses	$ 176,695	2020
Federal-capital losses	$ 35,673	2022
State-ordinary losses	$ 178,732	2019
State-capital losses	$ 25,524	2026

A valuation allowance is required when it is more likely than not that all or a portion of a deferred tax asset will not be realized. The Company assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased, or if objective negative evidence, in the form of cumulative losses, is no longer present and additional weight may be given to subjective evidence, such as projections for growth.

The Company has recorded a valuation allowance against certain jurisdictional net operating loss carryforwards and other tax attributes. As of December 31, 2018 and 2017, the total valuation allowance was $9,877.6 million and $8,063.0 million, respectively. During the years ended December 31, 2018 and 2017, the Company increased its valuation allowance in the amount of $1,814.6 million and $3,221.8 million, respectively.

The net increase in the Company's valuation allowance in 2018 was primarily driven by losses within jurisdictions unable to support recognition of a deferred tax asset, of which the largest jurisdiction was Luxembourg, where the Company had significant interest expense and losses on its investments in the equity of consolidated subsidiaries.

The net increase in the Company's valuation allowance in 2017 was primarily driven by: (i) $3,310.8 million related to losses within jurisdictions unable to support recognition of a deferred tax asset, of which the largest jurisdiction was Luxembourg, where the Company recognized a significant loss on its investment in the equity of consolidated subsidiaries, (ii) the establishment of a $479.7 million valuation allowance offsetting net deferred tax assets that was created in connection with the January 1, 2017 adoption of ASU No. 2016-16, "*Intra-Entity Transfers of Assets Other Than Inventory*" and that primarily relates to certain intangibles and tax deductible goodwill and (iii) $21.5 million relating to state tax benefits. This increase was partially offset by a $590.2 million reduction related to remeasurement of certain deferred tax assets resulting from the TCJA.

At December 31, 2018, the Company had the following significant valuation allowances (in thousands):

Jurisdiction	December 31, 2018
Ireland	$ 160,867
Luxembourg	$ 8,378,742
United States	$ 1,334,463

We have provided income taxes for earnings that are currently distributed as well as the taxes associated with certain earnings that are expected to be distributed in the future. No additional provision has been made for Irish and non-Irish income taxes on the undistributed earnings of subsidiaries or for unrecognized deferred tax liabilities for temporary differences related to basis differences in investments in subsidiaries as such earnings are expected to be indefinitely reinvested, the investments in subsidiaries are essentially permanent in duration. As of December 31, 2018, certain subsidiaries had approximately $1,231.8 million of cumulative undistributed earnings that have been permanently reinvested because our plans do not demonstrate a need to repatriate such earnings. A liability could arise if our intention to indefinitely reinvest such earnings were to change and amounts are distributed by such subsidiaries or if such subsidiaries are ultimately disposed. It is not practicable to estimate the additional income taxes related to indefinitely reinvested earnings or the basis differences related to investments in subsidiaries.

Uncertain Tax Positions

The Company 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 Company has taken positions on its tax returns that may be challenged by various tax authorities for which reserves have been established for tax-related uncertainties. The Company 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 Company'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 Company's effective tax rate in the year of resolution, while a resolution that is not favorable could increase the effective tax rate and may require the use of cash in the year of resolution. Uncertain tax positions are reviewed quarterly and adjusted as necessary when events occur that affect potential tax liabilities, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, identification of new issues and issuance of new legislation, regulations or case law.

As of December 31, 2018, the Company had total unrecognized income tax benefits of $479.4 million. If recognized in future years, $304.3 million of these currently unrecognized income tax benefits would impact the income tax provision and effective tax rate. As of December 31, 2017, the Company had total unrecognized tax benefits of $435.1 million. If recognized in future years, $289.9 million of these unrecognized income tax benefits would have impacted the income tax provision and effective tax rate. The following table summarizes the activity related to unrecognized income tax benefits during the years ended December 31, 2018, 2017 and 2016 (in thousands):

	Unrecognized Tax Benefit Federal, State, and Foreign Tax
UTB Balance at January 1, 2016	$ 316,247
Gross additions for current year positions	142,778
Gross reductions for prior period positions	(35,888)
Gross additions for prior period positions	2,111
Decrease due to lapse of statute of limitations	(3,085)
Additions related to acquisitions	2,350
Currency translation adjustment	88
UTB Balance at December 31, 2016	$ 424,601
Gross additions for current year positions	44,293
Gross reductions for prior period positions	(64,887)
Gross additions for prior period positions	22,765
Decrease due to lapse of statute of limitations	(13,151)
Currency translation adjustment	2,330
UTB Balance at December 31, 2017	$ 415,951
Gross additions for current year positions	36,088
Gross reductions for prior period positions	(3,570)
Gross additions for prior period positions	7,950
Decrease due to lapse of statute of limitations	(2,129)
Currency translation adjustment	(2,600)
UTB Balance at December 31, 2018	$ 451,690
Accrued interest and penalties	27,739
Total UTB balance including accrued interest and penalties	$ 479,429

The Company records accrued interest as well as penalties related to uncertain tax positions as part of the provision for income taxes. As of December 31, 2018 and 2017, $27.7 million and $19.2 million, respectively, of corresponding accrued interest and penalties is included in the Consolidated Balance Sheets, all of which is recorded in income taxes.

During the years ended December 31, 2018, 2017, and 2016, we recognized expense of $8.6 million, $1.4 million and $5.1 million, respectively, related to interest and penalties. The current portion of our UTB liability of $6.5 million is included in our Consolidated Balance Sheet as Accounts payable and accrued expenses. The non-current portion of our UTB liability is included in our Consolidated Balance Sheet as Other liabilities or, if and to the extent appropriate, as a reduction to Deferred tax assets.

Our subsidiaries file income tax returns in the countries in which they have operations. Generally, these countries have statutes of limitations ranging from 3 to 5 years. Certain subsidiary tax returns are currently under examination by taxing authorities, including U.S. tax returns for the 2011 through 2015 tax years by the Internal Revenue Service.

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

As of December 31, 2018, we may be subject to examination in the following major tax jurisdictions:

Jurisdiction	Open Years
Canada	2013 through 2018
India	2013 through 2018
Ireland	2014 through 2018
Luxembourg	2014 through 2018
United States - federal, state and local	2006 through 2018

NOTE 21. NET LOSS PER SHARE

The following is a reconciliation of the numerator and denominator of basic and diluted net loss per share attributable to Endo International plc ordinary shareholders for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Numerator:			
Loss from continuing operations	$ (961,767)	$ (1,232,711)	$ (3,223,772)
Less: Net income from continuing operations attributable to noncontrolling interests	—	—	16
Loss from continuing operations attributable to Endo International plc	$ (961,767)	$ (1,232,711)	$ (3,223,788)
Loss from discontinued operations, net of tax attributable to Endo International plc	(69,702)	(802,722)	(123,278)
Net loss attributable to Endo International plc	$ (1,031,469)	$ (2,035,433)	$ (3,347,066)
Denominator:			

For basic per share data—weighted average shares	223,960	223,198	222,651
Dilutive effect of ordinary share equivalents	—	—	—
For diluted per share data—weighted average shares	223,960	223,198	222,651

Basic net loss per share attributable to Endo International plc ordinary shareholders amounts are computed based on the weighted average number of ordinary shares outstanding during the period. Diluted net loss per share attributable to Endo International plc ordinary shareholders amounts are computed based on the weighted average number of ordinary shares outstanding and, if there is net income from continuing operations attributable to Endo International plc during the period, the dilutive impact of ordinary share equivalents outstanding during the period.

The dilutive effect of ordinary share equivalents is measured using the treasury stock method. Stock options and awards that have been issued but for which a grant date has not yet been established, such as the performance share units discussed in Note 18. Share-based Compensation, are not considered in the calculation of basic or diluted weighted average shares.

All potentially dilutive items were excluded from the diluted share calculation for the years ended December 31, 2018, 2017 and 2016 because their effect would have been anti-dilutive, as the Company was in a loss position.

NOTE 22. SAVINGS AND INVESTMENT PLAN AND DEFERRED COMPENSATION PLANS

Savings and Investment Plan

The Company maintains a defined contribution Savings and Investment Plan (the Endo 401(k) Plan) covering all U.S.-based eligible employees. The Company 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 Company's matching contributions, except that, for employees hired after 2017, the Company's matching contributions will vest ratably over a two-year period.

Costs incurred for contributions made by the Company to the Endo 401(k) Plan amounted to $6.4 million, $9.4 million and $11.5 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Directors Stock Election Plan

The Company 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 23. QUARTERLY FINANCIAL DATA (UNAUDITED)

The following table presents select unaudited financial data for each of the three-month periods ending March 31, 2018, June 30, 2018, September 30, 2018 and December 31, 2018, as well as the comparable 2017 periods (in thousands, except per share data):

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
2018 (1)				
Total revenues	$ 700,527	$ 714,696	$ 745,466	$ 786,389
Gross profit	$ 296,929	$ 332,791	$ 332,501	$ 353,175
Loss from continuing operations	$ (497,738)	$ (52,479)	$ (146,071)	$ (265,479)
Discontinued operations, net of tax	$ (7,751)	$ (8,388)	$ (27,134)	$ (26,429)
Net loss attributable to Endo International plc	$ (505,489)	$ (60,867)	$ (173,205)	$ (291,908)
Net loss per share attributable to Endo International plc ordinary shareholders—Basic:				
Continuing operations	$ (2.23)	$ (0.23)	$ (0.65)	$ (1.18)
Discontinued operations	(0.03)	(0.04)	(0.12)	(0.12)
Basic	$ (2.26)	$ (0.27)	$ (0.77)	$ (1.30)
Net loss per share attributable to Endo International plc ordinary shareholders—Diluted:				
Continuing operations	$ (2.23)	$ (0.23)	$ (0.65)	$ (1.18)
Discontinued operations	(0.03)	(0.04)	(0.12)	(0.12)
Diluted	$ (2.26)	$ (0.27)	$ (0.77)	$ (1.30)
Weighted average shares—Basic	223,521	223,834	224,132	224,353
Weighted average shares—Diluted	223,521	223,834	224,132	224,353
2017 (2)				
Total revenues	$ 1,037,600	$ 875,731	$ 786,887	$ 768,640
Gross profit	$ 368,638	$ 336,330	$ 272,365	$ 262,995
Loss from continuing operations	$ (165,423)	$ (696,020)	$ (99,687)	$ (271,581)
Discontinued operations, net of tax	$ (8,405)	$ (700,498)	$ 3,017	$ (96,836)
Net loss attributable to Endo International plc	$ (173,828)	$ (1,396,518)	$ (96,670)	$ (368,417)
Net loss per share attributable to Endo International plc ordinary shareholders—Basic:				
Continuing operations	$ (0.74)	$ (3.12)	$ (0.45)	$ (1.22)
Discontinued operations	(0.04)	(3.14)	0.02	(0.43)
Basic	$ (0.78)	$ (6.26)	$ (0.43)	$ (1.65)
Net loss per share attributable to Endo International plc ordinary shareholders—Diluted:				
Continuing operations	$ (0.74)	$ (3.12)	$ (0.45)	$ (1.22)
Discontinued operations	(0.04)	(3.14)	0.02	(0.43)
Diluted	$ (0.78)	$ (6.26)	$ (0.43)	$ (1.65)
Weighted average shares—Basic	223,014	223,158	223,299	223,322
Weighted average shares—Diluted	223,014	223,158	223,299	223,322

(1) Loss from continuing operations for the year ended December 31, 2018 was impacted by (i) acquisition-related and integration items of $6.8 million, $5.2 million, $1.3 million and $8.6 million during the first, second, third and fourth quarters, respectively, including charges due to changes in the fair value of contingent consideration of $6.8 million, $4.1 million, $0.8 million and $8.2 million, respectively, (ii) asset impairment charges of $448.4 million, $22.8 million, $142.2 million and $303.5 million during the first, second, third and fourth quarters, respectively, (iii) certain cost reductions and separation benefits incurred in connection with continued efforts to enhance the Company's operations and other miscellaneous costs of $49.0 million, $29.2 million, $4.0 million and $4.2 million during the first, second, third and fourth quarters, respectively, (iv) charges/(benefits) related to litigation-related and other contingent matters totaling $(2.5) million, $19.6 million, $(1.8) million and $(1.6) million during the first, second, third and fourth quarters, respectively, and (v) (gains) on sales of businesses and other assets of $(2.4) million, $(24.6) million, $(2.9) million and $(15.3) million during the first, second, third and fourth quarters, respectively.

(2) Loss from continuing operations for the year ended December 31, 2017 was impacted by (i) acquisition-related and integration items of $10.9 million, $4.2 million, $16.6 million and $26.4 million during the first, second, third and fourth quarters, respectively, including charges due to changes in the fair value of contingent consideration of $6.2 million, $2.0 million, $15.4 million and $26.4 million, respectively, (ii) asset impairment charges of $204.0 million, $725.0 million, $94.9 million and $130.4 million during the first, second, third and fourth quarters, respectively, (iii) certain cost reductions and separation benefits incurred in connection with continued efforts to enhance the Company's operations and other miscellaneous costs of $22.7 million, $24.6 million, $80.7 million and $84.5 million during the first, second, third and fourth quarters, respectively, (iv) charges/(benefits) related to litigation-related and other contingent matters totaling $0.9 million, $(2.6) million, $(12.4) million and $200.0 million during the first, second, third and fourth quarters, respectively, (v) loss on extinguishment of debt of $51.7 million during the second quarter and (vi) (gains) on sales of businesses and other assets of $(2.3) million, $(2.8) million and $(8.7) million during the first, third and fourth quarters, respectively. As previously reported in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, the third quarter numbers above reflect a $14.2 million correcting entry to increase asset impairment charges resulting from certain assets that should have been impaired during the second quarter.

Quarterly and year-to-date computations of per share amounts are made independently, therefore, the sum of the per share amounts for the quarters may not equal the per share amounts for the year.

As further described in Note 3. Discontinued Operations and Divestitures, we sold our Litha business in July 2017 and our Somar business in October 2017. Both of these businesses were part of our International Pharmaceuticals segment. Neither business met the requirements for presentation as discontinued operations. The operating results of the Astora business are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. For additional information, see Note 3. Discontinued Operations and Divestitures.

Exhibit 10.21

EXECUTION VERSION

ENDO HEALTH SOLUTIONS INC.

EXECUTIVE EMPLOYMENT AGREEMENT

THIS AGREEMENT (this "Agreement") is hereby entered into as of the 5th day of December, 2016 (the "Effective Date"), by and between Endo Health Solutions Inc. (the "Company"), a wholly-owned subsidiary of Endo International plc ("Endo"), and Antonio Pera ("Executive") (hereinafter collectively referred to as "the parties").

In consideration of the respective agreements of the parties contained herein, it is agreed as follows:

1. Term. The term of this Agreement shall be for the period commencing on the Effective Date and ending, subject to earlier termination as set forth in Section 6, on the third anniversary thereof (the "Employment Term").

2. Employment. During the Employment Term:

(a) Executive shall serve as President, Par Pharmaceutical and shall be assigned with the customary duties and responsibilities of such position. If Executive serves as a director of Endo or as a director or officer of any of Endo's affiliates, then Executive will fulfill Executive's duties as such director or officer without additional compensation.

(b) Executive shall report directly to Endo's Chief Executive Officer. Executive shall perform the duties, undertake the responsibilities and exercise the authority customarily performed, undertaken and exercised by persons situated in a similar executive capacity.

(c) Executive shall devote substantially full-time attention to the business and affairs of the Company and its affiliates. Executive may (i) serve on corporate civil, charitable or non-profit boards or committees, subject in all cases to the prior approval of the board of directors of Endo (the "Board") and other applicable written policies of the Company and its affiliates as in effect from time to time, and (ii) manage personal and family investments, participate in industry organizations and deliver lectures at educational institutions, so long as no such service or activity unreasonably interferes, individually or in the aggregate, with the performance of his responsibilities hereunder.

(d) Executive shall be subject to and shall abide by each of the personnel and compliance policies of the Company and its affiliates applicable and communicated in writing to senior executives.

(e) Executive shall provide services at his current location in Chestnut Ridge, New York, and will travel to the Company's U.S. headquarters in Malvern, Pennsylvania to the extent reasonably necessary and appropriate to fulfill his duties.

3. Annual Compensation.

(a) Base Salary. The Company agrees to pay or cause to be paid to Executive during the Employment Term a base salary at the rate of $460,000 per annum or such increased amount in accordance with this Section 3(a) (hereinafter referred to as the "Base Salary"). Such Base Salary shall be payable in accordance with the Company's customary practices applicable to its executives. Such Base Salary shall be reviewed at least annually by the Board or by the Compensation Committee of the Board (the "Committee"), with the first such planned review to occur in February 2017, and may be increased in the sole discretion of the Committee, but not decreased.

(b) Incentive Compensation. For each fiscal year of the Company ending during the Employment Term, effective as of the 2016 fiscal year, Executive shall be eligible to receive a target annual cash bonus of 55% of the Base Salary (such target bonus, as may hereafter be increased, the "Target Bonus") with the opportunity to receive a maximum annual cash bonus in accordance with the terms of the applicable annual cash bonus plan as in effect from time to time, subject to the achievement of performance targets set by the Committee. Such annual cash bonus ("Incentive Compensation") shall be paid in no event later than the 15th day of the third month following the end of the taxable year (of the Company or Executive, whichever is later) in which the performance targets have been achieved. If the parties (following good faith negotiation) fail to enter into a new employment agreement following expiration of the Employment Term and Executive terminates his employment within ninety (90) days following expiration of the Employment Term under circumstances that would have constituted Good Reason had such termination occurred during the Employment Term or if, during such 90-day period, the Company terminates Executive's employment under circumstances that would not have constituted Cause had such termination occurred during the Employment Term, then the Company shall pay

Executive a Pro-Rata Bonus (as defined in Section 8(b)(ii) hereof) in a lump sum at the time bonuses are payable to other senior executives of the Company.

4. Long-Term Compensation. During the Employment Term, Executive shall be eligible to receive equity-based compensation to be awarded in the sole discretion of the Committee, which may be subject to the achievement of certain performance targets set by the Committee. Beginning with grants made in 2017, Executive shall be eligible to receive equity-based compensation with a targeted grant date Fair Market Value (as defined in Endo's 2015 Stock Incentive Plan or any successor plan thereto) equal to 200% of Executive's Base Salary for such fiscal year, subject to any increase in the Committee's sole discretion. All such equity-based awards shall be subject to the terms and conditions set forth in the applicable plan and award agreements, and in all cases shall be as determined by the Committee; provided, that, such terms and conditions shall be no less favorable than those provided for other senior executives of the Company. If the parties (following good faith negotiation) fail to enter into a new employment agreement following expiration of the Employment Term and Executive terminates his employment within ninety (90) days following expiration of the Employment Term under circumstances that would have constituted Good Reason had such termination occurred during the Employment Term or if, during such 90-day period, the Company terminates Executive's employment under circumstances that would not have constituted Cause had such termination occurred during the Employment Term, then such termination of employment shall be treated as a termination of employment for "Good Reason" or without Cause, as applicable, for purposes of the performance-based restricted stock units held by Executive as of the date of such termination of employment (and such awards shall be treated in accordance with the terms of the applicable award agreements).

5. Other Benefits.

(a) Employee Benefits. During the Employment Term, Executive shall be entitled to participate in all employee benefit plans, practices and programs maintained by the Company or its affiliates and made available to employees generally, including, without limitation, all pension, retirement, profit sharing, savings, medical, hospitalization, disability, dental, life or travel accident insurance benefit plans, to the extent Executive is eligible under the terms of such plans. Executive's participation in such plans, practices and programs shall be on the same basis and terms as are applicable to employees of the Company generally. Executive is responsible for any taxes (other than taxes that are the Company's responsibility) that may be due based upon the value of the benefits provided.

(b) Executive Benefits. During the Employment Term, Executive shall be entitled to participate in all executive benefit or incentive compensation plans now maintained or hereafter established by the Company or its affiliates for the purpose of providing compensation and/or benefits to comparable executive employees of the Company including, but not limited to, the Company's deferred compensation plans and any supplemental retirement, deferred compensation, supplemental medical or life insurance or other bonus or incentive compensation plans. Unless otherwise provided herein, Executive's participation in such plans shall be on the same basis and terms, as other senior executives of the Company. No additional compensation provided under any of such plans shall be deemed to modify or otherwise affect the terms of this Agreement or any of Executive's entitlements hereunder. Executive is responsible for any taxes (other than taxes that are the Company's responsibility) that may be due based upon the value of the benefits provided.

(c) Fringe Benefits and Perquisites. During the Employment Term, Executive shall be entitled to all fringe benefits and perquisites generally made available by the Company or its affiliates to its senior executives in accordance with current Company policy. For the avoidance of doubt, Executive shall not be entitled to any excise tax gross-up under Section 280G or Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code") (or any successor provision), or any other tax gross-up.

(d) Business Expenses. Upon submission of proper invoices in accordance with the Company's normal procedures, Executive shall be entitled to receive prompt reimbursement of all reasonable out-of-pocket business, entertainment and travel expenses incurred by Executive in connection with the performance of Executive's duties hereunder. Such reimbursement shall be made in no event later than the end of the calendar year following the calendar year in which the expenses were incurred.

(e) Office and Facilities. During the Employment Term, Executive shall be provided with an appropriate office, with such secretarial and other support facilities as are commensurate with Executive's status with the Company and its affiliates, which facilities shall be adequate for the performance of Executive's duties hereunder.

(f) Vacation and Sick Leave. Executive shall be entitled, without loss of pay, to absent himself voluntarily from the performance of Executive's employment under this Agreement, pursuant to the following:

(i) Executive shall be entitled to annual vacation in accordance with the vacation policies of the Company as in effect from time to time, which shall in no event be less than four weeks per year; and

(ii) Executive shall be entitled to sick leave (without loss of pay) in accordance with the Company's policies as in effect from time to time.

6. Termination. The Employment Term and Executive's employment hereunder may be terminated under the circumstances set forth below; provided, however, that notwithstanding anything contained herein to the contrary, Executive shall not be considered to have terminated employment with the Company for purposes of this Agreement unless Executive would be considered to have incurred a "separation from service" from the Company within the meaning of Section 409A of the Code.

(a) Disability. The Company may terminate Executive's employment, on written notice to Executive after having reasonably established Executive's Disability. For purposes of this Agreement, Executive will be deemed to have a "Disability" if, as a result of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months, Executive is unable to perform the core functions of Executive's position (with or without reasonable accommodation) or is receiving income replacement benefits for a period of six (6) months or more under the Company's long-term disability plan. Executive shall be entitled to the compensation and benefits provided for under this Agreement for any period prior to Executive's termination by reason of Disability during which Executive is unable to work due to a physical or mental infirmity in accordance with the Company's policies for similarly-situated executives.

(b) Death. Executive's employment shall be terminated as of the date of Executive's death.

(c) Cause. The Company may terminate Executive's employment for Cause, effective as of the date of the Notice of Termination (as defined in Section 7 below) that notifies Executive of his termination for Cause. "Cause" shall mean, for purposes of this Agreement: (i) the continued failure by Executive to use good faith efforts in the performance of Executive's duties under this Agreement (other than any such failure resulting from Disability or other allowable leave of absence); (ii) the criminal felony indictment (or non-U.S. equivalent) of Executive by a court of competent jurisdiction; (iii) the engagement by Executive in misconduct that has caused, or, is reasonably likely to cause, material harm (financial or otherwise) to

the Company or any of its affiliates; such harm may be caused by, without limitation, (A) the unauthorized disclosure of material secret or Confidential Information (as defined in Section 10(d) below) of the Company or any of its affiliates, (B) the debarment of the Company or any of its affiliates by the U.S. Food and Drug Administration or any successor agency (the "FDA") or any non-U.S. equivalent, or (C) the registration of the Company or any of its affiliates with the U.S. Drug Enforcement Administration of any successor agency (the "DEA") to be revoked; (iv) the debarment of Executive by the FDA; (v) the continued material breach by Executive of this Agreement; or (vi) Executive makes, or is found to have made, a certification relating to the Company's financial statements and public filings that is known to Executive to be false. Notwithstanding the foregoing, prior to having Cause for Executive's termination (other than as described in clauses (ii) and (iv) above), the Company must deliver a written demand to Executive which specifically identifies the conduct that may provide grounds for Cause within ninety (90) calendar days of the Company's actual knowledge of such conduct, events or circumstances, and Executive must have failed to cure such conduct (if curable) within thirty (30) days after such demand. References to the Company in subsections (i) through (vi) of this paragraph shall also include affiliates of the Company.

(d) Without Cause. The Company may terminate Executive's employment without Cause. The Company shall deliver to Executive a Notice of Termination (as defined in Section 7 below) not less than thirty (30) days prior to the termination of Executive's employment without Cause and the Company shall have the option of terminating Executive's duties and responsibilities prior to the expiration of such thirty-day notice period provided the Company pays Base Salary through the end of such notice period.

(e) Good Reason. Executive may terminate employment with the Company for Good Reason (as defined below) by delivering to the Company a Notice of Termination not less than thirty (30) days prior to the termination of Executive's employment for Good Reason. The Company shall have the option of terminating Executive's duties and responsibilities prior to the expiration of such thirty-day notice period. For purposes of this Agreement, "Good Reason" means any of the following without Executive's written consent: (i) a material diminution in Executive's Base Salary, Target Bonus (provided that failure to earn a bonus equal to or in excess of the Target Bonus by reason of failure to achieve applicable performance goals shall not be deemed Good Reason) or benefits; (ii) a material diminution of his position, responsibilities, duties or authorities from those in effect as of the Effective Date; (iii) any change in reporting structure such that Executive is

required to report to someone other than Endo's Chief Executive Officer; (iv) any material breach by the Company of its obligations under this Agreement; or (v) the Company requiring Executive to be based at any office or location that increases the length of Executive's commute by more than fifty (50) miles. Executive shall provide notice of the existence of the Good Reason condition within ninety (90) days of the date Executive learns of the condition, and the Company shall have a period of thirty (30) days during which it may remedy the condition, and in case of full remedy such condition shall not be deemed to constitute Good Reason hereunder.

(f) Without Good Reason. Executive may voluntarily terminate Executive's employment without Good Reason by delivering to the Company a Notice of Termination not less than thirty (30) days prior to the termination of Executive's employment and the Company shall have the option of terminating Executive's duties and responsibilities prior to the expiration of such thirty-day notice period.

7. Notice of Termination. Any purported termination by the Company or by Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice that indicates a termination date, the specific termination provision in this Agreement relied upon and sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated. For purposes of this Agreement, no such purported termination of Executive's employment hereunder shall be effective without such Notice of Termination (unless waived by the party entitled to receive such notice).

8. Compensation Upon Termination. Upon termination of Executive's employment during the Employment Term, Executive shall be entitled to the following benefits:

(a) Termination by the Company for Cause or by Executive Without Good Reason. If Executive's employment is terminated by the Company for Cause or by Executive without Good Reason, the Company shall pay Executive all amounts earned or accrued hereunder through the termination date, including:

(i) any accrued and unpaid Base Salary, payable on the next payroll date;

(ii) any Incentive Compensation earned but unpaid in respect of any completed fiscal year preceding the termination date, payable at the time incentive compensation is paid to other senior executives;

(iii) reimbursement for any and all monies advanced or expenses incurred in connection with Executive's employment for reasonable and necessary expenses incurred by Executive on behalf of the Company for the period ending on the termination date, which amount shall be reimbursed within thirty (30) days of the Company's receipt of proper documentation from Executive;

(iv) any accrued and unpaid vacation pay, payable on the next payroll date;

(v) any previous compensation that Executive has previously deferred (including any interest earned or credited thereon), in accordance with the terms and conditions of the applicable deferred compensation plans or arrangements then in effect, to the extent vested as of Executive's termination date, paid pursuant to the terms of such plans or arrangements; and

(vi) any amount or benefit as provided under any benefit plan or program in accordance with the terms thereof; (the foregoing items in Sections 8(a)(i) through 8(a)(vi) being collectively referred to as the "Accrued Compensation").

(b) Termination by the Company for Disability. If Executive's employment is terminated by the Company for Disability, the Company shall pay Executive:

(i) the Accrued Compensation;

(ii) an amount equal to the Incentive Compensation that Executive would have been entitled to receive in respect of the fiscal year in which Executive's termination date occurs, had Executive continued in employment until the end of such fiscal year, which amount, determined based on actual performance for such year relative to the performance goals applicable to Executive (but without any exercise of negative discretion with respect to Executive in excess of that applied to either senior executives of the Company generally or in accordance with the Company's historical past practice), shall be multiplied by a fraction (A) the numerator of which is the number of days in such fiscal year through the termination date and (B) the denominator of which is 365 (the "Pro-Rata Bonus") and shall be payable in a lump sum payment at the time such bonus or incentive awards are payable to other participants. Further, upon Executive's Disability (irrespective of any termination of employment related thereto), the Company shall pay Executive for twenty-four (24) consecutive months

thereafter regular payments in the amount by which the monthly Base Salary exceeds Executive's monthly Disability insurance benefit; and

(iii) continued coverage for Executive and Executive's dependents under any health, medical, dental, vision or life insurance program or policy in which Executive was eligible to participate as of the time of Executive's employment termination, for two (2) years following such termination on the same basis as active employees, which such two year period shall run concurrently with the COBRA period, and which coverage shall become secondary to any coverage provided to Executive by a subsequent employer and to any Medicare coverage for which Executive becomes eligible; provided, however, the parties agree to cooperate such that the continued coverage is, to the extent practicable, provided in a manner so as to minimize adverse tax consequences to the Company.

(c) Termination By Reason of Death. If Executive's employment is terminated by reason of Executive's death, the Company shall pay Executive's beneficiaries:

(i) the Accrued Compensation;

(ii) the Pro-Rata Bonus; and

(iii) continued coverage for Executive's dependents under any health, medical, dental, vision or life insurance program or policy in which Executive was eligible to participate as of the time of Executive's employment termination, for two (2) years following such termination on terms no less favorable to Executive's dependents (including with respect to payment for the costs thereof) than those in effect immediately prior to such termination, which such two year period shall run concurrently with the COBRA period.

(d) Termination by the Company Without Cause or by Executive for Good Reason. If Executive's employment by the Company shall be terminated by the Company without Cause (other than on account of Executive's Disability or death) or by Executive for Good Reason, then, subject to Section 14(e) of this Agreement, Executive shall be entitled to the benefits provided in this Section 8(d):

(i) the Accrued Compensation;

(ii) the Pro-Rata Bonus;

(iii) in lieu of any further Base Salary or other compensation and benefits for periods subsequent to the termination date, an amount in cash, which amount shall be payable in a lump sum payment within sixty (60) days following such termination (subject to Section 9(c)), equal to two (2) times the sum of (A) Executive's Base Salary and (B) the Target Bonus; and

(iv) continued coverage under any health, medical, dental, vision or life insurance program or policy in which Executive was eligible to participate as of the time of Executive's employment termination for two (2) years following such termination on the same basis as active employees, which such two year period shall run concurrently with the COBRA period, and which coverage shall become secondary to any coverage provided to Executive by a subsequent employer and to any Medicare coverage for which Executive becomes eligible. Notwithstanding the above, in the event such continued coverage, by reason of change in the applicable law, may, in the Company's reasonable view, result in tax or other penalties on the Company, this provision shall terminate and the parties shall, in good faith, negotiate for a substitute provision that provides substantially similar benefit to Executive but does not result in such tax or other penalties.

(e) No Mitigation. Executive shall not be required to mitigate the amount of any payment provided for under this Section 8 by seeking other employment or otherwise and, except as provided in Section 8(b)(iii) and 8(d)(iv) above, no such payment shall be offset or reduced by the amount of any compensation or benefits provided to Executive in any subsequent employment. Further, the Company's obligations to make any payments hereunder shall not be subject to or affected by any set-off, counterclaim or defense which the Company may have against Executive.

9. Certain Tax Treatment.

(a) Golden Parachute Tax. To the extent that the payments and benefits provided under this Agreement and benefits provided to, or for the benefit of, Executive under any other plan or agreement of the Company or any of its affiliates (such payments or benefits are collectively referred to as the "Payments") would be subject to the excise tax (the "Excise Tax") imposed under Section 4999 of the Code or any successor provision thereto, or any similar tax imposed by state or local law, then Executive may, in his sole discretion, (except as provided herein below) waive the right to receive any payments or distributions (or a portion thereof) by the Company in the nature of compensation to or for Executive's

benefit if and to the extent necessary so that no Payment to be made or benefit to be provided to Executive shall be subject to the Excise Tax (such reduced amount is hereinafter referred to as the "Limited Payment Amount"), but only if such reduction results in a higher after-tax payment to Executive after taking into account the Excise Tax and any additional taxes (including federal, state and local income taxes, employment, social security and Medicare taxes and all other applicable taxes) Executive would pay if such Payments and benefits were not reduced. If so waived, the Company shall reduce or eliminate the Payments provided under Section 8, to effect the provisions of this Section 9 based upon Section 9(b) below. The determination of the amount of Payments that would be required to be reduced to the Limited Payment Amount pursuant to this Agreement and the amount of such Limited Payment Amount shall be made, at the Company's expense, by a reputable accounting firm selected by Executive and reasonably acceptable to the Company (the "Accounting Firm"). The Accounting Firm shall provide its determination (the "Determination"), together with detailed supporting calculations and documentation to the Company and Executive within ten (10) days of the date of termination, if applicable, or such other time as specified by mutual agreement of the Company and Executive, and if the Accounting Firm determines that no Excise Tax is payable by Executive with respect to the Payments, it shall furnish Executive with an opinion reasonably acceptable to Executive that no Excise Tax will be imposed with respect to any such Payments. The Determination shall be binding, final and conclusive upon the Company and Executive, absent manifest error. For purposes of making the calculations required by this Section 9(a), the Accounting Firm may make reasonable assumptions and approximations concerning applicable taxes and rates, and rely on reasonable, good faith interpretations concerning the application of the Code, and other applicable legal authority. In furtherance of the above, to the extent requested by Executive, the Company shall cooperate in good faith in valuing, and the Accounting Firm shall value, services to be provided by Executive (including Executive refraining from performing services pursuant to any covenant not to compete) before, on or after the date of the transaction which causes the application of Section 4999 of the Code, such that payments in respect of such services may be considered to be "reasonable compensation" within the meaning of the regulations under Section 4999 of the Code.

(b) Ordering of Reduction. In the case of a reduction in the Payments pursuant to Section 9(a), the Payments will be reduced in the following order: (i) payments that are payable in cash that are valued at full value under Treasury Regulation Section 1.280G-1, Q&A 24(a) will be reduced (if necessary, to zero), with

amounts that are payable last reduced first; (ii) payments and benefits due in respect of any equity valued at full value under Treasury Regulation Section 1.280G-1, Q&A 24(a), with the highest values reduced first (as such values are determined under Treasury Regulation Section 1.280G-1, Q&A 24) will next be reduced; (iii) payments that are payable in cash that are valued at less than full value under Treasury Regulation Section 1.280G-1, Q&A 24, with amounts that are payable last reduced first, will next be reduced; (iv) payments and benefits due in respect of any equity valued at less than full value under Treasury Regulation Section 1.280G-1, Q&A 24, with the highest values reduced first (as such values are determined under Treasury Regulation Section 1.280G-1, Q&A 24) will next be reduced; and (v) all other non-cash benefits not otherwise described in clauses (ii) or (iv) will be next reduced pro-rata.

(c) Section 409A. The parties intend for the payments and benefits under this Agreement to be exempt from Section 409A of the Code or, if not so exempt, to be paid or provided in a manner which complies with the requirements of such section, and intend that this Agreement shall be construed and administered in accordance with such intention. In the event the Company determines that a payment or benefit under this Agreement may not be in compliance with Section 409A of the Code, subject to Section 5(c) herein, the Company shall reasonably confer with Executive in order to modify or amend this Agreement to comply with Section 409A of the Code and to do so in a manner to best preserve the economic benefit of this Agreement. Notwithstanding anything contained herein to the contrary, to the extent required in order to avoid accelerated taxation and/or tax penalties under Section 409A of the Code, (i) no amounts shall be paid to Executive under Section 8 of this Agreement until Executive would be considered to have incurred a "separation from service" from the Company within the meaning of Section 409A of the Code, (ii) amounts that would otherwise be payable and benefits that would otherwise be provided pursuant to this Agreement during the six-month period immediately following Executive's separation from service shall instead be paid on the first business day after the date that is six (6) months following Executive's separation from service (or death, if earlier), with interest for any cash payments so delayed, from the date such cash amounts would otherwise have been paid at the short-term applicable federal rate, compounded semi-annually, as determined under Section 1274 of the Code for the month in which the payment would have been made but for the delay in payment required to avoid the imposition of an additional rate of tax on Executive, (iii) each amount to be paid or benefit to be provided under this Agreement shall be construed as a separately identified payment for purposes of Section 409A of the Code, (iv) any

payments that are due within the "short term deferral period" as defined in Section 409A of the Code shall not be treated as deferred compensation unless applicable law requires otherwise and (v) amounts reimbursable to Executive under this Agreement shall be paid to Executive on or before the last day of the year following the year in which the expense was incurred and the amount of expenses eligible for reimbursement (and in-kind benefits provided to Executive) during any one (1) year may not effect amounts reimbursable or provided in any subsequent year.

10. Records and Confidential Data.

(a) Executive acknowledges that in connection with the performance of Executive's duties during the Employment Term, the Company and its affiliates will make available to Executive, or Executive will develop and have access to, certain Confidential Information (as defined below) of the Company and its affiliates. Executive acknowledges and agrees that any and all Confidential Information learned or obtained by Executive during the course of Executive's employment by the Company or otherwise, whether developed by Executive alone or in conjunction with others or otherwise, shall be and is the property of the Company and its affiliates.

(b) Confidential Information will be kept confidential by Executive, will not be used in any manner that is detrimental to the Company or its affiliates, will not be used other than in connection with Executive's discharge of Executive's duties hereunder, and will be safeguarded by Executive from unauthorized disclosure; provided, however, that Confidential Information may be disclosed by Executive (v) to the Company and its affiliates, or to any authorized agent or representative of any of them, (w) in connection with performing his duties hereunder, (x) without limiting Section 10(g) of this Agreement, when required to do so by law or requested by a court, governmental agency, legislative body, arbitrator or other person with apparent jurisdiction to order him to divulge, disclose or make accessible such information, provided that Executive, to the extent legally permitted, notifies the Company prior to such disclosure, (y) in the course of any proceeding under Section 11 or 12 of this Agreement or Section 6 of the Release, subject to the prior entry of a confidentiality order or (z) in confidence to an attorney or other professional advisor for the purpose of securing professional advice, so long as such attorney or advisor is subject to confidentiality restrictions no less restrictive than those applicable to Executive hereunder.

(c) On Executive's last day of employment with the Company, or at such earlier date as requested by the Company, (i) Executive will return to the Company all written Confidential Information that has been provided to, or prepared by, Executive; (ii) at the election of the Company, Executive will return to the Company or destroy all copies of any analyses, compilations, studies or other documents prepared by Executive or for Executive's use containing or reflecting any Confidential Information; and (iii) Executive will return all Company property. Executive shall deliver to the Company a document certifying his compliance with this Section 10(c).

(d) For the purposes of this Agreement, "Confidential Information" shall mean all confidential and proprietary information of the Company and its affiliates, including, without limitation,

(i) trade secrets concerning the business and affairs of the Company and its affiliates, product specifications, data, know-how, formulae, compositions, processes, non-public patent applications, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current, and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, computer software and programs (including object code and source code), computer software and database technologies, systems, structures, and architectures (and related formulae, compositions, processes, improvements, devices, know-how, inventions, discoveries, concepts, ideas, designs, methods and information);

(ii) information concerning the business and affairs of the Company and its affiliates (which includes unpublished financial statements, financial projections and budgets, unpublished and projected sales, capital spending budgets and plans, the names and backgrounds of key personnel, to the extent not publicly known, personnel training and techniques and materials) however documented; and

(iii) notes, analysis, compilations, studies, summaries, and other material prepared by or for the Company or its affiliates containing or based, in whole or in part, on any information included in the foregoing. For purposes of this Agreement, Confidential Information shall not include and Executive's obligations shall not extend to (i) information that is generally available to the public, (ii) information obtained by Executive

other than pursuant to or in connection with this employment, (iii) information that is required to be disclosed by law or legal process, and (iv) Executive's rolodex and similar address books, including electronic address books, containing contact information.

(e) Nothing herein or elsewhere shall preclude Executive from retaining and using (i) his personal papers and other materials of a personal nature, including, without limitation, photographs, contacts, correspondence, personal diaries, and personal files (so long as no such materials are covered by any Company hold order), (ii) documents relating to his personal entitlements and obligations, and (iii) information that is necessary for his personal tax purposes.

(f) Executive's obligations under this Section 10 shall survive the termination of the Employment Term.

(g) Pursuant to Section 1833(b) of the Defend Trade Secrets Act of 2016, Executive acknowledges that Executive shall not have criminal or civil liability under any federal or State trade secret law for the disclosure of a trade secret that (i) is made (A) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney and (B) solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Nothing in this Agreement is intended to conflict with Section 1833(b) of the Defend Trade Secrets Act of 2016 or create liability for disclosures of trade secrets that are expressly allowed by such Section.

(h) Notwithstanding anything set forth in this Agreement to the contrary, Executive shall not be prohibited from reporting possible violations of federal or state law or regulation to any governmental agency or entity or making other disclosures that are protected under the whistleblower provisions of federal or state law or regulation, nor is Executive required to notify the Company regarding any such reporting, disclosure or cooperation with the government.

11. Covenant Not to Solicit, Not to Compete, Not to Disparage, to Cooperate in Litigation and Not to Cooperate with Non-Governmental Third Parties.

(a) Covenant Not to Solicit. To protect the Confidential Information and other trade secrets of the Company and its affiliates as well as the goodwill and competitive business of the Company and its affiliates, Executive agrees, during the Employment Term and for a period of eighteen (18) months after Executive's cessation of employment with the Company, not to solicit or participate in or

assist in any way in the solicitation of any customers, clients, suppliers, employees or agents of the Company or its affiliates. For purposes of this covenant, "solicit" or "solicitation" means directly or indirectly influencing or attempting to influence any customers, clients, suppliers, employees or agents of the Company or its affiliates to cease doing business with, or to reduce the level of business with, the Company and its affiliates or, with respect to employees or exclusive agents, to become employed or engaged by any other person, partnership, firm, corporation or other entity. Executive agrees that the covenants contained in this Section 11(a) are reasonable and desirable to protect the Confidential Information of the Company and its affiliates; provided, that solicitation through general advertising not targeted at the Company's or its affiliates' employees or the provision of references shall not constitute a breach of such obligations.

(b) Covenant Not to Compete.

(i) The Company and its affiliates are currently engaged in the business of branded and generic pharmaceuticals, with a focus on product development, clinical development, manufacturing, distribution and sales & marketing. To protect the Confidential Information and other trade secrets of the Company and its affiliates as well as the goodwill and competitive business of the Company and its affiliates, Executive agrees, during the Employment Term and for a period of eighteen (18) months after Executive's cessation of employment with the Company, that Executive will not anywhere in the world where, at the time of Executive's termination of employment, the Company develops, manufactures, distributes, markets or sells its products, except in the course of Executive's employment hereunder, directly or indirectly manage, operate, control, or participate in the management, operation, or control of, be employed by, associated with, or in any manner connected with, lend Executive's name to, or render services or advice to, any third party or any business whose products or services compete in whole or in part with the products or services (both on the market and in development) material to the Company or any business unit on the termination date that constitutes more than 5% of the Company's revenue on the termination date (a "Competing Business"); provided, however, that Executive may in any event (x) own up to a 5% passive ownership interest in any public or private entity and (y) serve on the board of any Competing Business that competes with the business of the Company and its affiliates as an

immaterial part of its overall business, provided that he recuses himself fully and completely from all matters relating to such business.

(ii) For purposes of this Section 11(b), any third party or any business whose products compete includes any entity with which the Company or its affiliates has had a product(s) licensing agreement during the Employment Term and any entity with which the Company or any of its affiliates is at the time of termination actively negotiating, and eventually concludes within twelve (12) months of the Employment Term, a commercial agreement.

(iii) Notwithstanding the foregoing, it shall not be a violation of this Section 11(b), for Executive to provide services to (or engage in activities involving): (A) a subsidiary, division or affiliate of a Competing Business where such subsidiary, division or affiliate is not engaged in a Competing Business and Executive does not provide services to, or have any responsibilities regarding, the Competing Business; (B) any entity that is, or is a general partner in, or manages or participates in managing, a private or public fund (including, without limitation, a hedge fund) or other investment vehicle, which is engaged in venture capital investments, leveraged buy-outs, investments in public or private companies, other forms of private or alternative equity transactions, or in public equity transactions, and that might make an investment which Executive could not make directly, provided that in connection therewith, Executive does not provide services to, engage in activities involved with, or have any responsibilities regarding a Competing Business; and (C) an affiliate of a Competing Business if Executive does not provide services, directly or indirectly, to such Competing Business and the basis of the affiliation is solely due to common ownership by a private equity or similar investment fund; provided, that, in each case, Executive shall remain bound by all other post-employment obligations under this Agreement including, but not limited to, Executive's obligations under Sections 10, 11(a), (c) and (d) herein; provided, further, that Executive's provision of services to (or engagement in activities involving) any entity described in clauses (A) or (B) of this Section 11(b)(iii) shall be subject to the prior approval of the Board.

(c) Nondisparagement. Executive covenants that during and following the Employment Term, Executive will not disparage or encourage or induce others to disparage the Company or its affiliates, together with all of their respective past

and present directors and officers, as well as their respective past and present managers, officers, shareholders, partners, employees, agents, attorneys, servants and customers and each of their predecessors, successors and assigns (collectively, the "Company Entities and Persons"); provided, that such limitation shall extend to past and present managers, officers, shareholders, partners, employees, agents, attorneys, servants and customers only in their capacities as such or in respect of their relationship with the Company and its affiliates. The Company agrees that, during and following the Employment Term, neither the Company nor any director or officer, will issue any written statement that disparages Executive to any third parties or otherwise encourage or induce others to disparage Executive, and the Company shall instruct its officers and directors not to make any statement that disparages Executive to any third parties or otherwise encourage or induce others to disparage Executive. The term "disparage" includes, without limitation, comments or statements adversely affecting in any manner (i) the conduct of the business of the Company Entities and Persons or Executive, or (ii) the business reputation of the Company Entities and Persons or Executive. Nothing in this Agreement is intended to or shall prevent either party from providing, or limiting testimony in any judicial, administrative or legal process or otherwise as required by law, prevent either party from engaging in truthful testimony pursuant to any proceeding under this Section 11 or Section 12 below or Section 6 of the Release or prevent Executive from making statements in the course of doing his normal duties for the Company.

(d) Cooperation in Any Investigations and Litigation; No Cooperation with Non-Governmental Third Parties. Executive agrees that Executive will reasonably cooperate with the Company and its affiliates, and its counsel, (i) in connection with any investigation, inquiry, administrative proceeding or litigation relating to any matter in which Executive was involved or of which Executive has knowledge as a result of Executive's service with the Company by providing truthful information, and (ii) in all matters concerning requests for information about the services or advice Executive provides to the Company during his employment with Endo, its affiliates and their predecessors. Such cooperation shall be subject to Executive's business and personal commitments and shall not require Executive to cooperate against his own legal interests or the legal interests of any future employer of Executive. The Company agrees to promptly reimburse Executive for reasonable expenses reasonably incurred by Executive, in connection with Executive's cooperation pursuant to this Section 11(d) (including travel expenses at the level of travel permitted by this Agreement and reasonable attorney fees in the event Executive reasonably determines that separate legal

counsel for Executive is appropriate). Such reimbursements shall be made as soon as practicable, and in no event later than the calendar year following the year in which the expenses are incurred. Executive also shall not (i) support (financially or otherwise), counsel or assist any attorneys or their clients or any other non-governmental person in the presentation or prosecution of, (ii) encourage any non-governmental person to raise, or (iii) suggest or recommend to any non-governmental person that such person could or should raise, in each case, any disputes, differences, grievances, claims, charges, or complaints against the Company and/or its affiliates that (x) arises out of, or relates to, any period of time on or prior to Executive's last day of employment with the Company or (y) involves any information Executive learned during his employment with the Company; provided, that, after eighteen (18) months following Executive's termination of employment with the Company, such prohibition shall not extend to any such actions taken by Executive on behalf of (A) Executive's then current employer, (B) any entity with respect to which Executive is then a member of the board of directors or managers (as applicable) or (C) any non-publicly traded entity with respect to which Executive is a 5% or more equity owner (or any affiliate of any such entities referenced in clauses (A), (B) or (C)). Executive agrees that, in the event Executive is subpoenaed by any person or entity (including, but not limited to, any government agency) to give testimony (in a deposition, court proceeding or otherwise) which in any way relates to Executive's employment by the Company, Executive will, to the extent not legally prohibited from doing so, give prompt notice of such request to the Chief Legal Officer of the Company so that the Company may contest the right of the requesting person or entity to such disclosure before making such disclosure. Nothing in this provision shall require Executive to violate Executive's obligation to comply with valid legal process.

(e) Blue Pencil. It is the intent and desire of Executive and the Company that the provisions of this Section 11 be enforced to the fullest extent permissible under the laws and public policies as applied in each jurisdiction in which enforcement is sought. If any particular provision of this Section 11 shall be determined to be invalid or unenforceable, such covenant shall be amended, without any action on the part of either party hereto, to delete therefrom the portion so determined to be invalid or unenforceable, such deletion to apply only with respect to the operation of such covenant in the particular jurisdiction in which such adjudication is made.

(f) Survive. Executive's obligations under this Section 11 shall survive the termination of the Employment Term.

12. Remedies for Breach of Obligations under Sections 10 or 11 hereof. Executive acknowledges that the Company and its affiliates will suffer irreparable injury, not readily susceptible of valuation in monetary damages, if Executive breaches Executive's obligations under Sections 10 or 11 hereof. Accordingly, Executive agrees that the Company and its affiliates will be entitled, in addition to any other available remedies, to obtain injunctive relief against any breach or prospective breach by Executive of Executive's obligations under Sections 10 or 11 hereof in any Federal or state court sitting in the State of Delaware or, at the Company's election, in any other state in which Executive maintains Executive's principal residence or Executive's principal place of business**.** Executive hereby submits to the non-exclusive jurisdiction of all those courts for the purposes of any actions or proceedings instituted by the Company or its affiliates to obtain that injunctive relief, and Executive agrees that process in any or all of those actions or proceedings may be served by registered mail, addressed to the last address provided by Executive to the Company, or in any other manner authorized by law.

13. Representations and Warranties.

(a) The Company represents and warrants that (i) it is fully authorized by action of the Board (and of any other person or body whose action is required) to enter into this Agreement and to perform its obligations under it, (ii) the execution, delivery and performance of this Agreement by it does not violate any applicable law, regulation, order, judgment or decree or any agreement, arrangement, plan or corporate governance document (x) to which it is a party or (y) by which it is bound, and (iii) upon the execution and delivery of this Agreement by the parties, this Agreement shall be its valid and binding obligation, enforceable against it in accordance with its terms, except to the extent that enforceability may be limited by applicable bankruptcy, insolvency or similar laws affecting the enforcement of creditors' rights generally.

(b) Executive represents and warrants to the Company that the execution and delivery by Executive of this Agreement do not, and the performance by Executive of Executive's obligations hereunder will not, with or without the giving of notice or the passage of time, or both: (a) violate any judgment, writ, injunction, or order of any court, arbitrator, or governmental agency applicable to Executive; or (b) conflict with, result in the breach of any provisions of or the termination of, or constitute a default under, any agreement to which Executive is a party or by which Executive is or may be bound.

14. Miscellaneous.

(a) Successors and Assigns.

(i) This Agreement shall be binding upon and shall inure to the benefit of the Company, its successors and permitted assigns and the Company shall require any successor or permitted assign to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such succession or assignment had taken place. The Company may not assign or delegate any rights or obligations hereunder except to any of its affiliates or to a successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company. The term the "Company" as used herein shall include a corporation or other entity acquiring all or substantially all the assets and business of the Company (including this Agreement) whether by operation of law or otherwise.

(ii) Neither this Agreement nor any right or interest hereunder shall be assignable or transferable by Executive, Executive's beneficiaries or legal representatives, except by will or by the laws of descent and distribution. This Agreement shall inure to the benefit of and be enforceable by Executive's legal personal representatives.

(b) Notice. For the purposes of this Agreement, notices and all other communications provided for in the Agreement (including the Notice of Termination) shall be in writing and shall be deemed to have been duly given when personally delivered or sent by Certified mail, return receipt requested, postage prepaid, addressed to the respective addresses last given by each party to the other; provided, that all notices to the Company shall be directed to the attention of the Chief Legal Officer of the Company. All notices and communications shall be deemed to have been received on the date of delivery thereof or on the third business day after the mailing thereof, except that notice of change of address shall be effective only upon receipt.

(c) Indemnification. Executive shall be indemnified by the Company as, and to the extent, to the maximum extent permitted by applicable law as provided in the memorandum and articles of association of Endo. In addition, the Company agrees to continue and maintain, at the Company's sole expense, a directors' and officers' liability insurance policy covering Executive both during and the Employment Term and while the potential liability exists (but in no event longer than six (6) years, if such limitation applies to all other individuals covered by

such policy) after the Employment Term, that is no less favorable than the policy covering Board members and other executive officers of the Company from time to time. The obligations under this paragraph shall survive any termination of the Employment Term.

(d) Withholding. The Company shall be entitled to withhold the amount, if any, of all taxes of any applicable jurisdiction required to be withheld by an employer with respect to any amount paid to Executive hereunder. The Company, in its sole and absolute discretion, shall make all determinations as to whether it is obligated to withhold any taxes hereunder and the amount thereof.

(e) Release of Claims. The termination benefits described in Section 8(d) of this Agreement shall be conditioned on Executive delivering to the Company, a signed release of claims in the form of Exhibit A hereto within forty-five (45) days or twenty-one (21) days, as may be applicable under the Age Discrimination in Employment Act of 1967, as amended by the Older Workers Benefit Protection Act, following Executive's termination date, and not revoking Executive's consent to such release of claims within seven (7) days of such execution; provided, however, that Executive shall not be required to release any rights Executive may have to be indemnified by, or be covered under any directors' and officers' liability insurance of, the Company under Section 14(c) of this Agreement.

(f) Resignation as Officer or Director. Upon a termination of employment for any reason, Executive shall, resign each position (if any) that Executive then holds as an officer or director of the Company and any of its affiliates. Executive's execution of this Agreement shall be deemed the grant by Executive to the officers of the Company of a limited power of attorney to sign in Executive's name and on Executive's behalf any such documentation as may be required to be executed solely for the limited purposes of effectuating such resignations.

(g) Executive Acknowledgement. Executive acknowledges the Common Stock Ownership Guidelines for Non-Employee Directors and Executive Management of Endo International plc, as may be amended from time to time, and Endo's compensation recoupment policy, as may be amended from time to time.

(h) Modification. No provision of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing and signed by Executive and the Company. No waiver by either party hereto at any time of any breach by the other party hereto of, or compliance with, any

condition or provision of this Agreement to be performed by such other party shall be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time. No agreement or representations, oral or otherwise, express or implied, with respect to the subject matter hereof have been made by either party which are not expressly set forth in this Agreement.

(i) Effect of Other Law. Anything herein to the contrary notwithstanding, the terms of this Agreement shall be modified to the extent required to meet the provisions of the Sarbanes-Oxley Act of 2002, Section 409A, or other federal law applicable to the employment arrangements between Executive and the Company. Any delay in providing benefits or payments, any failure to provide a benefit or payment, or any repayment of compensation that is required under the preceding sentence shall not in and of itself constitute a breach of this Agreement; provided, however, that the Company shall provide economically equivalent payments or benefits to Executive to the extent permitted by law.

(j) Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware applicable to contracts executed in and to be performed entirely within such State, without giving effect to the conflict of law principles thereof. Any dispute hereunder may be adjudicated in any Federal or state court sitting in the State of Delaware or, at the Company's election, in any other state in which Executive maintains Executive's principal residence or Executive's principal place of business.

(k) No Conflicts. (A) Executive represents and warrants to the Company that Executive is not a party to or otherwise bound by any agreement or arrangement (including, without limitation, any license, covenant, or commitment of any nature), or subject to any judgment, decree, or order of any court or administrative agency, that would conflict with or will be in conflict with or in any way preclude, limit or inhibit Executive's ability to execute this Agreement or to carry out Executive's duties and responsibilities hereunder. (B) The Company represents and warrants to Executive that the Company is not a party to or otherwise bound by any agreement or arrangement (including, without limitation, any license, covenant, or commitment of any nature), or subject to any judgment, decree, or order of any court or administrative agency, that would conflict with or will be in conflict with or in any way preclude, limit or inhibit the Company's ability to execute this Agreement or to carry out the Company's duties and responsibilities hereunder.

(l) Severability. The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof.

(m) Inconsistencies. In the event of any inconsistency between any provision of this Agreement and any provision of any employee handbook, personnel manual, program, policy, or arrangement of the Company or its affiliates (including, without limitation, any provisions relating to notice requirements and post-employment restrictions), the provisions of this Agreement shall control, unless Executive otherwise agrees in a writing that expressly refers to the provision of this Agreement whose control he is waiving.

(n) Beneficiaries/References. In the event of Executive's death or a judicial determination of his incompetence, references in this Agreement to Executive shall be deemed, where appropriate, to refer to his beneficiary, estate or other legal representative.

(o) Survivorship. Except as otherwise set forth in this Agreement, the respective rights and obligations of the parties hereunder shall survive the Employment Term and any termination of Executive's employment. Without limiting the generality of the forgoing, the provisions of Section 8, 10, 11, and 12 shall survive the Employment Term.

(p) Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto and supersedes all prior agreements, understandings and arrangements, oral or written, between the parties hereto with respect to the subject matter hereof.

(q) Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

15. Certain Rules of Construction.

(a) The headings and subheadings set forth in this Agreement are inserted for the convenience of reference only and are to be ignored in any construction of the terms set forth herein.

(b) Wherever applicable, the neuter, feminine or masculine pronoun as used herein shall also include the masculine or feminine, as the case may be.

(c) The term “including” is not limiting and means “including without limitation.”

(d) References in this Agreement to any statute or statutory provisions include a reference to such statute or statutory provisions as from time to time amended, modified, reenacted, extended, consolidated or replaced (whether before or after the date of this Agreement) and to any subordinate legislation made from time to time under such statute or statutory provision.

(e) References to “writing” or “written” include any non-transient means of representing or copying words legibly, including by facsimile or electronic mail.

(f) References to “$” are to United States Dollars.

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized officer and Executive has executed this Agreement as of the day and year first above written.

ENDO HEALTH SOLUTIONS INC.

By: /s/ Paul Campanelli
Name: Paul Campanelli
Title: Chief Executive Officer

EXECUTIVE

By: /s/ Antonio Pera
Name: Antonio Pera
Title: President, Par Pharmaceutical Companies, Inc.

EXHIBIT A

FORM OF RELEASE AGREEMENT

THIS RELEASE AGREEMENT (the "Release") is made by and Antonio Pera ("Executive") and Endo Health Solutions, Inc. (the "Company").

1. FOR AND IN CONSIDERATION of the payments and benefits provided in Section 8(d)(ii), (iii) and (iv) of the Employment Agreement between Executive and the Company dated as of December 5, 2016, (the "Employment Agreement"), Executive, for himself, his successors and assigns, executors and administrators, now and forever hereby releases and discharges the Company, together with all of its past and present parents, subsidiaries, and affiliates, together with each of their officers, directors, stockholders, partners, employees, agents, representatives and attorneys, and each of their subsidiaries, affiliates, estates, predecessors, successors, and assigns (hereinafter collectively referred to as the "Releasees") from any and all rights, claims, charges, actions, causes of action, complaints, sums of money, suits, debts, covenants, contracts, agreements, promises, obligations, damages, demands or liabilities of every kind whatsoever, in law or in equity, whether known or unknown, suspected or unsuspected, which Executive or Executive's executors, administrators, successors or assigns ever had, now has or may hereafter claim to have by reason of any matter, cause or thing whatsoever; arising from the beginning of time up to the date Executive executes the Release: (i) relating in any way to Executive's employment relationship with the Company or any of the Releasees, or the termination of Executive's employment relationship with the Company or any of the Releasees; (ii) arising under or relating to the Employment Agreement; (iii) arising under any federal, local or state statute or regulation, including, without limitation, the Age Discrimination in Employment Act of 1967, as amended by the Older Workers Benefit Protection Act, Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act of 1990, the Employee Retirement Income Security Act of 1974, the Equal Pay Act, any claim arising under the provisions of the False Claims Act; 31 U.S.C.A. § 3730, including, but not limited to, any right to personal gain with respect to any claim asserted under its "qui tam" provisions, Sections 1981 through 1988 of Title 42 of the United States Code, the Immigration Reform and Control Act, the Workers Adjustment and Retraining Notification Act, the Occupational Safety and Health Act, the Family and Medical Leave Act, the Fair Labor Standards Act of 1938, Executive Order 11246, the Pennsylvania Human Relations Act, the Pennsylvania Whistleblower Law and/or the applicable state or local law or ordinance against discrimination, each as amended; (iv) relating to wrongful employment termination or breach of contract; or (v) arising under or relating to any policy, agreement, understanding or promise, written or oral, formal or informal, between the Company and any of the Releasees and Executive; provided, however, that notwithstanding the foregoing, nothing contained in the Release shall in any way diminish or impair: (a) any rights Executive may have, from and after the date the Release is executed; (b) any rights to indemnification that may exist from time to time

under the Company's certificate of incorporation or bylaws, or state law or any other indemnification agreement entered into between Executive and the Company; (c) any rights Executive may have under any applicable general liability and/or directors and officers insurance policy maintained by the Company; (d) any rights Executive may have to vested benefits under employee benefit plans or incentive compensation plans of the Company; (e) any rights Executive may have as a general shareholder of the Company; (f) Executive's ability to bring appropriate proceedings to enforce the Release; (g) any rights to the payments and benefits provided in Section 8(d)(ii), (iii) and (iv) of the Employment Agreement; and (h) any rights or claims Executive may have that cannot be waived under applicable law (collectively, the "Excluded Claims"). Executive further acknowledges and agrees that, except with respect to Excluded Claims, the Company and the Releasees have fully satisfied any and all obligations whatsoever owed to Executive arising out of Executive's employment with the Company or any of the Releasees, and that no further payments or benefits are owed to Executive by the Company or any of the Releasees. Nothing in this Release is intended to prohibit or restrict Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment; provided that Executive hereby waives the right to recover any monetary damages or other relief against any Releasees.

2. Executive understands and agrees that, except for the Excluded Claims, Executive has knowingly relinquished, waived and forever released any and all rights to any personal recovery in any action or proceeding that may be commenced on Executive's behalf arising out of the aforesaid employment relationship or the termination thereof, including, without limitation, claims for back pay, front pay, liquidated damages, compensatory damages, general damages, special damages, punitive damages, exemplary damages, costs, expenses and attorneys' fees.

3. Executive acknowledges and agrees that Executive has been advised to consult with an attorney of Executive's choosing prior to signing the Release. Executive understands and agrees that Executive has the right and has been given the opportunity to review the Release with an attorney of Executive's choice should Executive so desire. Executive also agrees that Executive has entered into the Release freely and voluntarily. Executive further acknowledges and agrees that Executive has had at least [twenty-one (21)][forty-five (45)] calendar days to consider the Release, although Executive may sign it sooner if Executive wishes. In addition, once Executive has signed the Release, Executive shall have seven (7) additional days from the date of execution to revoke Executive's consent and may do so by writing to: _____. The Release shall not be effective, and no payments shall be due hereunder, earlier than the eighth (8th) day after Executive shall have executed the Release and returned it to the Company, assuming that Executive had not revoked Executive's consent to the Release prior to such date.

4. It is understood and agreed by Executive that any payment made to Executive is not to be construed as an admission of any liability whatsoever on the part of the Company or any

of the other Releasees, by whom liability is expressly denied.

5. The Release is executed by Executive voluntarily and is not based upon any representations or statements of any kind made by the Company or any of the other Releasees as to the merits, legal liabilities or value of Executive's claims. Executive further acknowledges that Executive has had a full and reasonable opportunity to consider the Release and that Executive has not been pressured or in any way coerced into executing the Release.
6. The exclusive venue for any disputes arising hereunder shall be the state or federal courts located in the State of Delaware or, at the Company's election, in any other state in which Executive maintains Executive's principal residence or Executive's principal place of business, and each of the parties hereto irrevocably waives, to the fullest extent permitted by law, any objection which it may now or hereafter have to the laying of the venue of any such proceeding brought in such a court and any claim that any such proceeding brought in such a court has been brought in an inconvenient forum. Each of the parties hereto also agrees that any final and unappealable judgment against a party hereto in connection with any action, suit or other proceeding may be enforced in any court of competent jurisdiction, either within or outside of the United States. A certified or exemplified copy of such award or judgment shall be conclusive evidence of the fact and amount of such award or judgment.

7. The Release and the rights and obligations of the parties hereto shall be governed and construed in accordance with the laws of the State of Delaware. If any provision hereof is unenforceable or is held to be unenforceable, such provision shall be fully severable, and this document and its terms shall be construed and enforced as if such unenforceable provision had never comprised a part hereof, the remaining provisions hereof shall remain in full force and effect, and the court construing the provisions shall add as a part hereof a provision as similar in terms and effect to such unenforceable provision as may be enforceable, in lieu of the unenforceable provision.
8. The Release shall inure to the benefit of and be binding upon the Company and its successors and assigns.

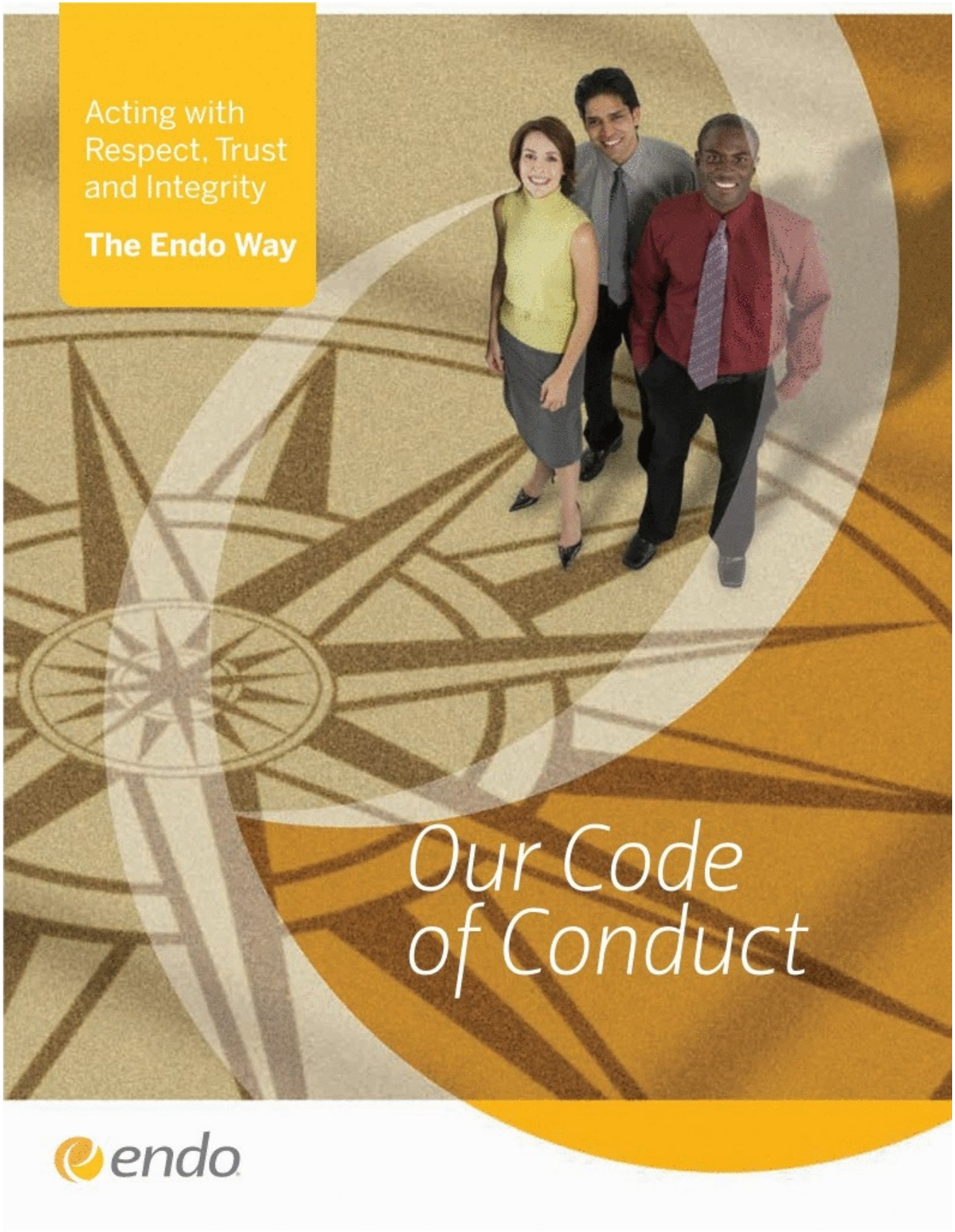
IN WITNESS WHEREOF, Executive and the Company have executed the Release as of the date and year provided below.

IMPORTANT NOTICE: BY SIGNING BELOW YOU RELEASE AND GIVE UP ANY AND ALL LEGAL CLAIMS, KNOWN AND UNKNOWN, THAT YOU MAY HAVE AGAINST THE COMPANY AND RELATED PARTIES.

_____ _____

ENDO HEALTH SOLUTIONS INC. Antonio Pera

Dated:_____ Dated:_____


Acting with
Respect, Trust
and Integrity
The Endo Way
Our Code
of Conduct
endo

A Message from Our Chief Executive Officer

Dear Colleagues,

At Endo International plc and its subsidiaries ("Endo"), we are driven by our shared vision of being a highly focused generics and specialty branded pharmaceutical company, delivering quality medicines to patients in need through excellence in development, manufacturing and commercialization.

In order to achieve our aspiration, we must maintain a competitive advantage in today's marketplace by living our Core Values in a manner that reflects our guiding principles of respect, trust and integrity—this is **The Endo Way.**

Our reputation—as a company, as leaders and as individuals—depends on our approach to ethics. Today's compliance environment is highly dynamic and our approach to ethics and compliance must be unwavering, proactive and strategic as regulatory and public expectations continue to evolve.

Endo's Code of Conduct ("our Code") is designed to help you make the right decisions. Sound, ethical decision-making 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. **The Endo Way** enables us to earn and keep the trust and confidence of our healthcare customers, patients, regulators and shareholders.

As an Endo employee, you are required to review our Code and adhere to all aspects of it in order to ensure that we uphold our ethical responsibilities to our customers, the healthcare community, patients, regulators, shareholders and the communities where we work and live. Our Code reflects not only our guiding principles but also your personal accountability to sustain our reputation for ethical behavior.

Sincerely,

Paul Campanelli
President and Chief Executive Officer
Endo International plc

A Message from Endo's Chief Compliance Officer

Dear Colleagues,

Today's compliance environment is highly dynamic and our approach to ethics and compliance must be unwavering, proactive and strategic as regulatory and public expectations continue to evolve. Our reputation—as a company, as leaders and as individuals—depends on our approach to ethics.

Endo's Code of Conduct is designed to enable us to apply our guiding principles of respect, trust and integrity to our day-to-day activities. Ethical decision-making based on our Code of Conduct is the foundation of our success and results in a consistent approach to compliance across our company.

What does this mean for you as an Endo employee, officer, director or agent?

First, take personal responsibility so that your actions and decisions are consistent with our Code of Conduct and the Company policies applicable to your role. Second, foster and promote a culture of ethical behavior in every aspect of your job—particularly when leading or working in teams and collaborative settings. Third, know the rules and seek guidance if you have questions about the right thing to do. Finally, speak up—respectfully and appropriately—if you are aware of potential behavior that is inconsistent with our Code of Conduct, values or Company policies.

Our Department's mission is to maintain an effective corporate-wide compliance program that enables us to achieve our strategic vision and business goals in an ethical, compliant and sustainable manner. Our compliance program is founded on clear rules of business conduct along with ongoing training, education and communication, and monitoring of our program to assess and enhance its effectiveness. 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.

Our Code of Conduct is not intended to provide an exhaustive list of every policy you need to know; rather it is an ethical compass to guide your daily activities. Beyond the Code, there are numerous resources along with instructive Q&A's to help you. Our Department strives to provide leadership, resources and a solutions orientation based on trusted partnerships and mutual respect.

No written code or policy can guarantee compliance with law or ethical decision-making. Each of us has a personal responsibility to act with respect, trust and integrity: it is everyone's business and the Endo Way.

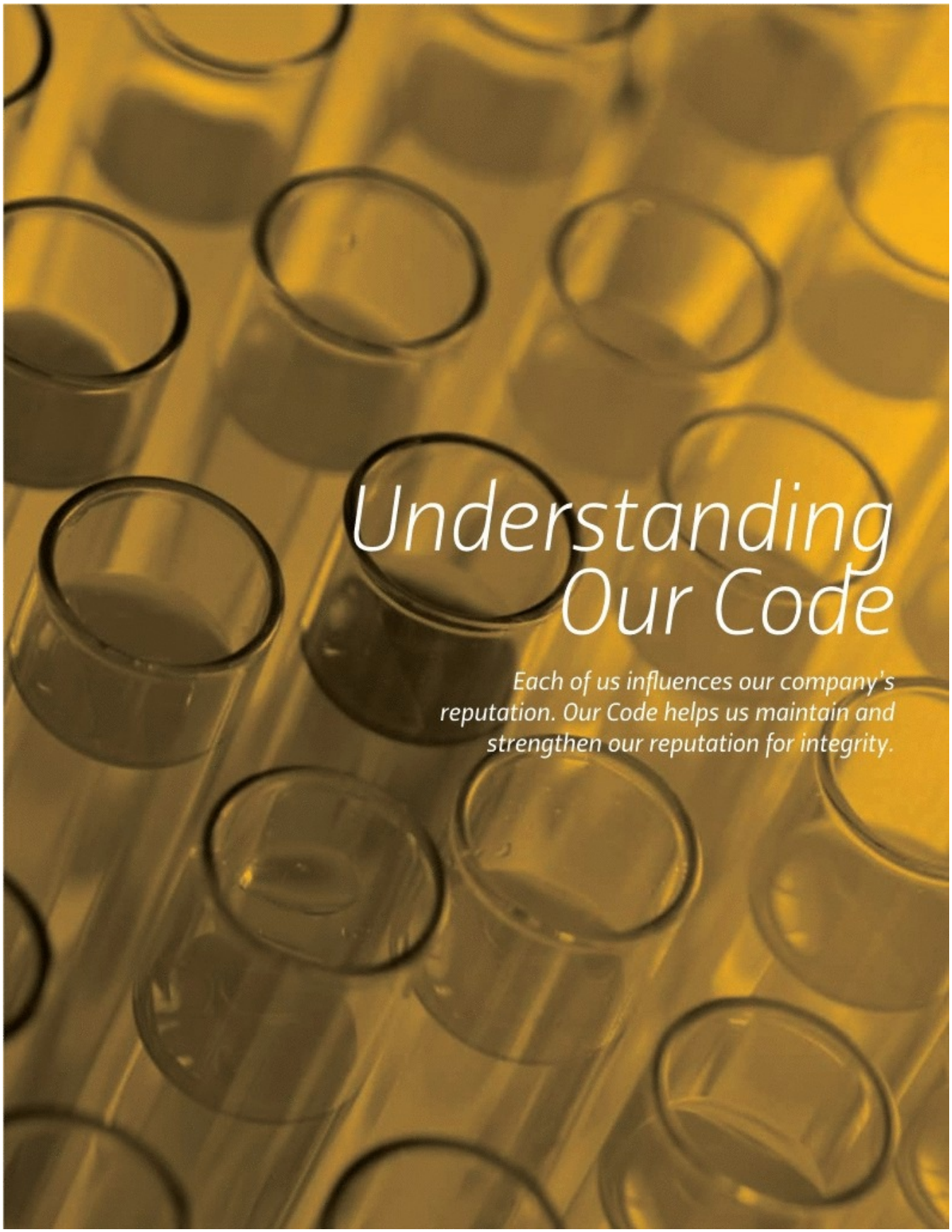
Sincerely,

Susan Williamson

Susan Williamson
Senior Vice President and Chief Compliance Officer

Table of Contents

The Endo Code of Conduct is not a contract of employment. Endo reserves the right to modify any aspect of its compliance program, including this Code of Conduct, without prior notice. If there is a conflict between this Code and a Company policy, the policy currently in effect shall govern.



Understanding Our Code

Each of us influences our company's reputation. Our Code helps us maintain and strengthen our reputation for integrity.

Understanding Our Code

To help us act with respect, trust and integrity, Endo's Code of Conduct defines how we interact with patients, healthcare providers, payors, suppliers, government officials, the healthcare community, shareholders and each other. This Code applies to every person conducting business for Endo and to all Endo locations, affiliates and subsidiaries. Due to local law in some countries, some provisions may be supplemented by policies or standards to address local requirements. When Endo standards differ from local requirements, always follow the higher standard.

What is Expected of Everyone

Each of us is individually accountable for acting in accordance with this Code. All officers and employees must certify, in writing or electronically, that they have reviewed, read, understand, and shall abide by this Code. Any waiver for a person covered by the Code must be submitted to and approved by the Chief Compliance Officer.

The Endo Way

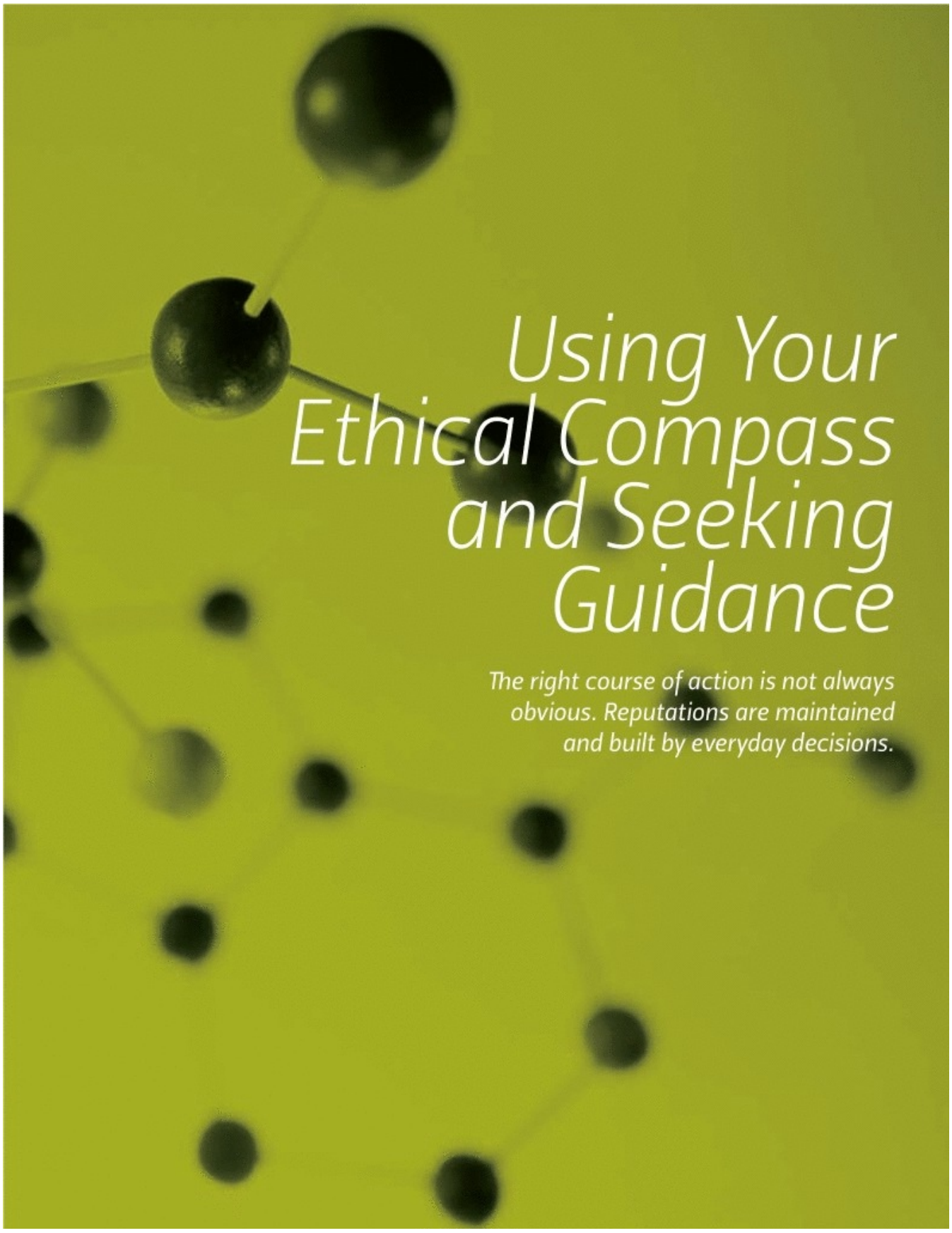
- Act with honesty, fairness, integrity and personal accountability to protect our reputation
- Never compromise your integrity for the sake of "making the numbers" or due to pressure from a supervisor
- Respect fellow staff, government officials, business partners, competitors, customers and patients
- Know and follow the rules and seek guidance
- Sustain a culture where ethical conduct is expected, recognized and valued
- Report known or suspected violations of this Code
- Cooperate with investigations—always be forthcoming and tell the truth
- No form of retaliation or intimidation against an employee who makes a good-faith report of a suspected violation or participates in good faith in any investigation of a suspected violation will be tolerated

What is Expected of Our Leaders

As a leader, you serve as an ethical role model and are held to a higher standard. This means proactively identifying questionable conduct, preventing problems before they occur and setting the right tone with your reports and across the Company. You are also accountable for undertaking reasonable efforts to ensure that contractors or agents working under your management control adhere to the Code.

The Endo Way

- Foster a culture that focuses on integrity, ethics and compliance, collaboration, quality and patient safety as expected behaviors
- Guide your teams and reinforce the importance of our Code, our Vision, Core Values and Company policies along with timely completion of ethics and compliance training
- Partner with compliance leaders
- Take reasonable steps to make sure that vendors and consultants act in a manner consistent with this Code
- Proactively prevent and respond to ethics and compliance issues in a way that always reinforces the appropriateness of raising issues
- Take appropriate disciplinary actions in consultation with human resources, compliance leaders and legal contacts



Using Your Ethical Compass and Seeking Guidance

The right course of action is not always obvious. Reputations are maintained and built by everyday decisions.

Using Your Ethical Compass and Seeking Guidance

Our Code of Conduct is not a substitute for understanding and following the policies applicable to your role. Although the Code cannot anticipate every situation, it can and should serve as an ethical compass. If you have any doubts about a potential course of action, ask yourself the following questions:

- Is it legal?
- Is it ethical and consistent with our Core Values?
- Is it consistent with our Code of Conduct?
- Am I being truthful and honest?
- Will it reflect positively on our reputation for integrity?
- Would I feel comfortable if it was reported in the news or to someone I respect?

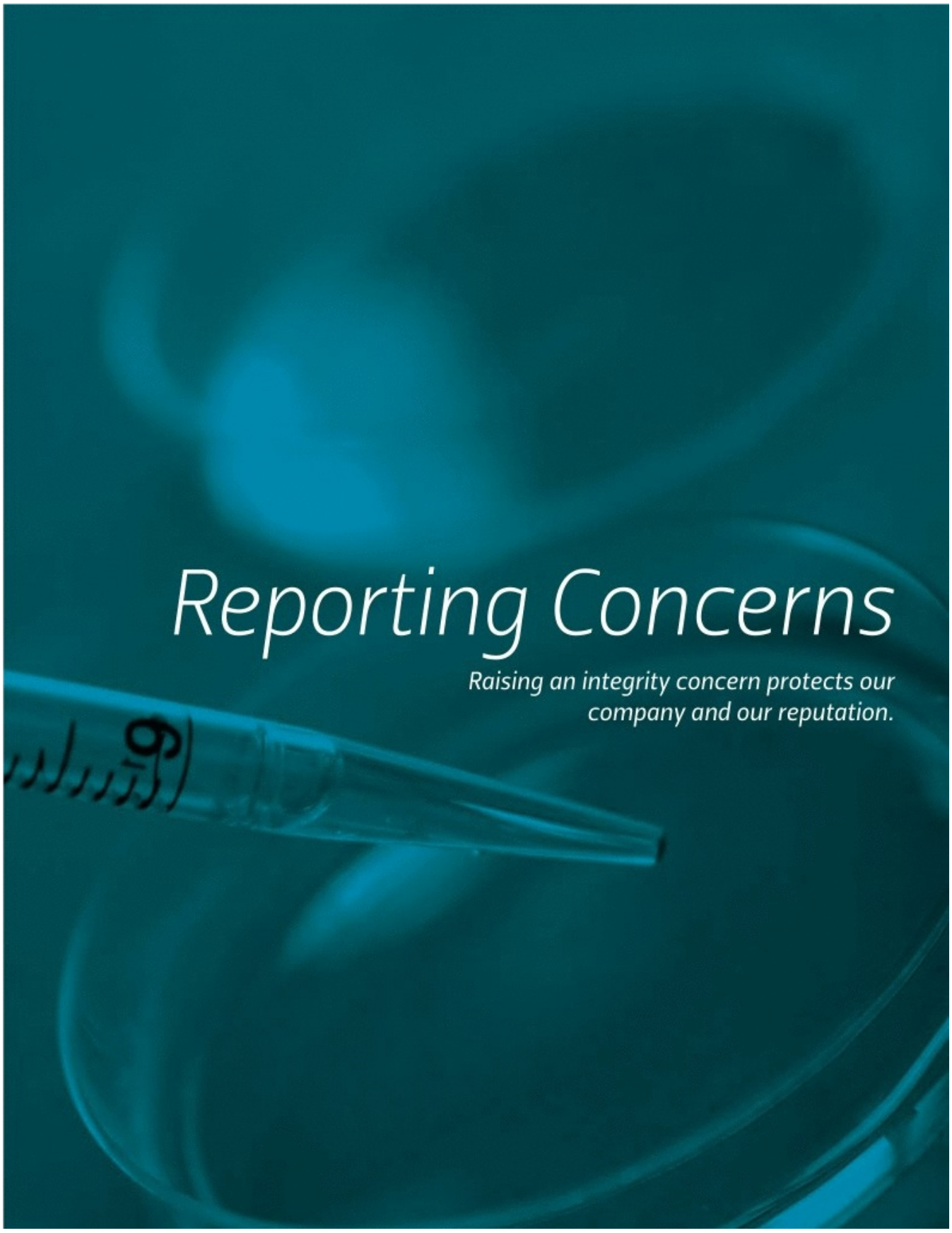
If you still have questions, always seek additional guidance. You are not alone when faced with a tough ethical decision. If the answer to any of these questions is "no," do not do it. It is never permissible to ignore our Code of Conduct to achieve a business objective.

Resources for Seeking Guidance

- Your Manager
- Business Unit Compliance Leader
- Corporate Compliance and Business Practices Department
- Human Resources
- Legal Department
- Ethics Hotline

I have questions about whether a proposed business plan complies with Company policy but worry that my manager will assume I do not know how to perform my job. What should I do?

Endo encourages and expects employees to raise questions. Managers are expected to foster an environment where everyone feels comfortable doing so and are likely the best people to speak with first. Your business compliance leader, human resource or legal contact will also be in a position to provide guidance. You may also raise the issue through Endo's Ethics Hotline. If you have a question, it's your responsibility and Endo's expectation that you'll ask.


Reporting Concerns
Raising an integrity concern protects our company and our reputation.

Reporting Concerns

You play an important role in helping us meet the standards reflected in our Code of Conduct. When you raise an issue, we can look into the matter, take timely and appropriate action and make corrections, if necessary. If you observe or have knowledge of potentially inappropriate conduct, you have an obligation to report your concerns. Endo has established procedures for handling reported concerns.

The Endo Way

- Promptly raise concerns about a potential violation of law, Company policies or our Code of Conduct
- Foster an "open door" policy and maintain awareness of the variety of channels to raise and report concerns
- If a concern you raise is not resolved, raise it through another channel
- Fully cooperate with Endo investigations and always be forthright and honest

How to Raise a Concern

Endo offers several channels to raise concerns. You should use the channel that is most comfortable to you. As a general matter, your supervisor or manager may be in the best position to address an issue. However, that is not your only option. Potential channels to report a concern are:

- Direct Management or Senior Management
- Business Compliance Leaders
- Corporate Compliance and Business Practices Department
- Business Legal Contacts
- Business Human Resource Leaders

Endo also has in place an Ethics Hotline where reports can be made at any time by phone or online. All reports, whether submitted by phone or online, will be issued a reference number. You may use that reference number to provide further information or check the status of an investigation by phone or online at www.endo.ethicspoint.com, regardless of how you originally used the hotline. You should note that investigations take time and our ability to share information may be limited.

Anonymity and Confidentiality

Where permitted by local laws, you may use the Ethics Hotline to anonymously report known or suspected issues or ask a question. Some countries prohibit or discourage anonymous reporting or restrict the types of information that may be reported. If you use the Ethics Hotline from one of those countries, you will be advised of any specific reporting restrictions. Toll-free international numbers are available at www.endo.ethicspoint.com for every country in which Endo has employees.

The information you report will be treated as confidentially as possible. Your report will be shared only with those who need to know about it to answer your question or to investigate the matter. Should you choose to identify yourself, Endo will make every reasonable effort to keep your identity confidential, while at the same time meeting its obligation to fairly investigate the matter. In some instances, Endo may be required to reveal your identity, if known.

Investigations of Possible Misconduct

Endo takes reports of alleged misconduct very seriously and will investigate them to determine if any law, Company policy or aspect of our Code of Conduct may have been violated.

Non-Retaliation Policy

No form of retaliation or intimidation against an employee who makes a good-faith report of a suspected violation or participates in good faith in any investigation of a suspected violation will be tolerated. Employees who engage in retaliation or intimidation will be subject to disciplinary action, up to and including termination.

Endo reserves the right to discipline anyone who knowingly makes a false accusation, provides false information about the Company or has acted improperly.

Disciplinary Actions

Any employee who violates this Code, Company policy or applicable laws may be subject to disciplinary action, up to and including termination. Misconduct may include violations of this Code and Company policies, failure to raise a known or potential issue, not cooperating with an investigation or intimidating or engaging in retaliation against an employee who raises a potential issue or provides information during an investigation.

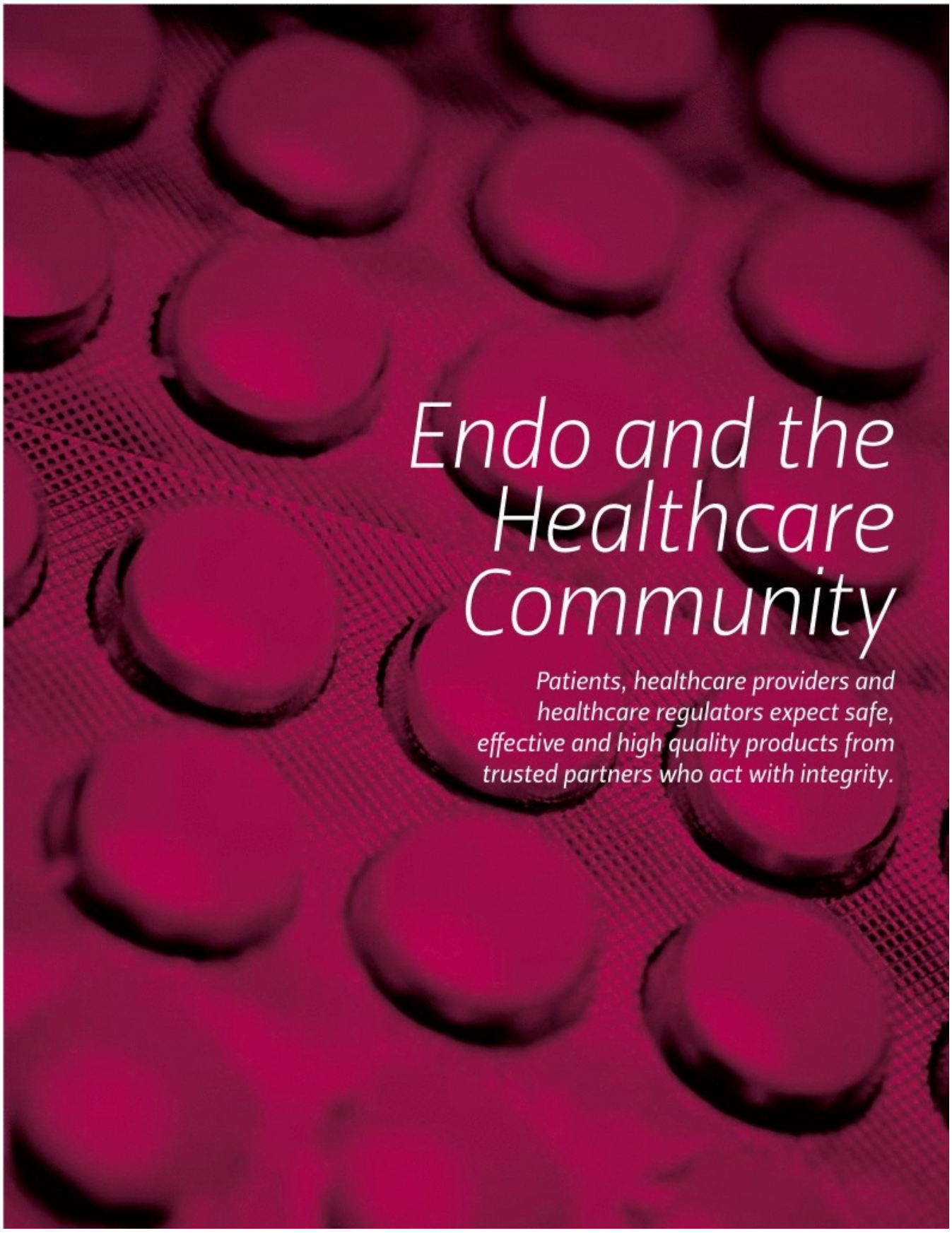
Ethics Hotline

800-305-1563

Visit
www.endo.ethicspoint.com
to report a concern
or access toll-free
international numbers

One of my reports asked me to discuss a potential issue. How should I approach him?

Your reaction is extremely important. Allow adequate time to discuss the potential concern in an appropriate location. Listen as much as possible and do not be defensive. You should not feel required to give an immediate answer. Reassure him that the Company takes reports of misconduct very seriously. Depending on the potential concern, you may need to involve HR, your management, business compliance leader or legal contact. Treat an employee who raises an issue with respect and do not retaliate against or intimidate the employee in any manner.



Endo and the Healthcare Community

Patients, healthcare providers and healthcare regulators expect safe, effective and high quality products from trusted partners who act with integrity.

Endo and the Healthcare Community

We act responsibly, lawfully and with integrity in our relationships with members of the healthcare community—patients, patient groups, healthcare providers and healthcare regulators. Maintaining these principles in our daily activities is critical to sustaining trust in our products and fulfilling our vision and mission.

The Endo Way

- Adopt good operating and quality principles throughout our research, development, manufacturing and distribution activities, always focusing on patients
- Communicate with healthcare providers, patients and the public in a fair and balanced manner
- Interact with healthcare providers ethically and in accordance with applicable laws and regulations when promoting or providing information about our products
- Continuously monitor the safety, performance and quality of our products
- Promote transparency and cooperate with healthcare regulators by always providing truthful and complete information in a manner that facilitates trust and partnership

Good Operating Practices

Maintaining the quality of our products is critical to patient safety and to our success. Quality is what patients and the healthcare community expect of us. We meet these expectations by embedding quality principles into our operational activities and by adhering to applicable laws and practices. Endo is committed to continuous quality and process improvement across our business segments.

Special rules and regulations apply to the handling, storage and transfer of controlled substances. We must strictly comply with these requirements and our policies and procedures related to controlled substances. If you have any knowledge or suspicion about the improper handling, transfer, loss or diversion of a controlled substance, you are required to immediately report it to your manager or the Ethics Hotline.

Failure to report suspected diversion or a theft of our products is a violation of this Code and may subject an employee to disciplinary action, up to and including termination.

The Endo Way

- Maintain in each business unit written policies and procedures that define our standards for delivering high-quality products
- Complete training in a timely manner
- Maintain accurate and complete records and conduct routine audits
- Be diligent in identifying and preventing practices that could impact the quality of our products
- Report potential instances of non-compliance
- Promote continuous process improvement

We are behind schedule and under pressure to increase production. May we slightly modify a few manufacturing steps to speed things up?

Although we strive to continuously make our manufacturing processes more efficient, our commitment to quality is foremost. Always follow our quality standards and approval processes when considering a modification to a manufacturing process. Discuss your potential process improvement with your management and site quality leader to assess if it is feasible and consistent with our quality standards.

Monitoring the Safety, Performance and Quality of Our Products

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.

Endo operates across multiple industries with timing and reporting procedures that vary. We conduct periodic reviews and analyses of safety information and always take responsible and appropriate actions to improve the safety profile of our products.

The Endo Way

- Report all adverse events and complaints that you become aware of for any Endo product
- Follow the instructions that are provided to you and are standard in your business unit for reporting safety information
- Provide prompt notification, in accordance with the requirements of Company policy, to your business unit of any potential safety issue or incident
- If you are unsure whether an adverse event has occurred or whether an incident is reportable, report it through the designated channels and allow our experts to make that determination

While on vacation, a fellow traveler mentioned that he felt nauseous after taking one of our products. Do I have to report this conversation?

Yes. Although our product may not have caused an adverse event, those qualified and responsible for such determinations should be notified and make the decision. Report the conversation for appropriate review and analysis so that any potential reporting requirements are met and we fulfill our commitment to patient health and safety.

Promoting Our Products

Endo is committed to promoting its products based on patient needs and the merits of each product in a transparent, legal and accurate manner.

Our interactions with healthcare professionals should be focused on educating them about our products, and supporting their medical education and training needs to lead to improved patient care. We encourage truthful and ethical communications that will help healthcare professionals make informed and independent decisions about how they can best use our products on label for their patients.

The ideal location for providing educational information about Endo products is in a physician or healthcare provider's office, a hospital or other clinical setting. Local law or industry codes may allow for certain discussions outside of those settings in specific circumstances. Always follow the Company policy applicable to your business unit. If you have any questions, contact your business unit compliance leader or the Corporate Compliance and Business Practices Department.

The Endo Way

- Only use promotional materials and communications that have been approved by appropriate disciplines, are on label, accurate, not misleading and comply with applicable legal, regulatory and local standards
- Do not promote the use of any product beyond its approved labeling and authorization
- Promotional materials must be previously approved, consistent with approved labeling information and be supported, as appropriate, by scientific evidence
- Provide fair balance by presenting the full picture of our products, including a summary of all safety information
- Do not mischaracterize or make unfair comments about competitors' products

A doctor on my call plan mentioned that her colleague used one of our products with good results for patients not suffering from the conditions indicated in our label. She asked for information from scientific literature about off-label uses. I am aware of recent studies from an industry conference I attended. Can I share that information?

No. Your obligation is to refer her to our medical information contacts who are able to provide complete and accurate scientific information in a manner that is consistent with Company policy. In accordance with Company policy, provide her with the necessary information to complete documentation for an unsolicited request for information or provide the number to directly call our medical information staff. When promoting a product, only discuss on-label information.

Interacting with Healthcare Professionals and Healthcare Providers

Endo educates healthcare professionals and healthcare providers about our products, collaborates on research, relies on their expertise as advisers and trains them on the use of our products. Our interactions must always reflect our commitment to integrity, compliance, accuracy and transparency, including adherence to our standards on prohibiting bribery and corruption.

Endo also promotes scientific integrity and does not allow business pressures to influence in any way this valuable collaboration that advances scientific and medical understanding, including the appropriate use of our products, the management of diseases and patient care.

The Endo Way

- Engage healthcare professionals only when there is a bona fide need and always pay a fair fee consistent with our Fair Market Value policies and applicable local law whenever a fee is to be paid
- Never attempt to buy business or provide anything of value to influence any healthcare provider's judgment to choose an Endo product nor create any misperception that Endo is doing so
- Provide appropriate instruction, education and training on the safe and effective use of our products
- Maintain transparency regarding all your interactions with healthcare professionals and providers, institutions and others in the healthcare community
- Do not accept, pay for, or otherwise promote or encourage patient referrals in exchange, or as an improper inducement for the purchase, lease, recommendation or use of any Endo product

An approved physician speaker is presenting at an Endo sponsored educational program for patients who may benefit from using one of our products. Can the physician customize the handouts and revise our approved slides?

No. Our educational and promotional materials are developed through a rigorous review process. It is never permissible to use unapproved materials or modify approved materials or visual aids.

We are having a hard time introducing local physicians to one of our recently approved products. One recommendation is to conduct a study and enroll local physicians as investigators. This will allow them to get acquainted with our product and enhance our efforts to introduce it. Is this ok?

No. Studies must have scientific merit, may only be conducted to serve a scientific purpose and never should be intended to "seed" the market or promote a product.

Government Inspections and Requests

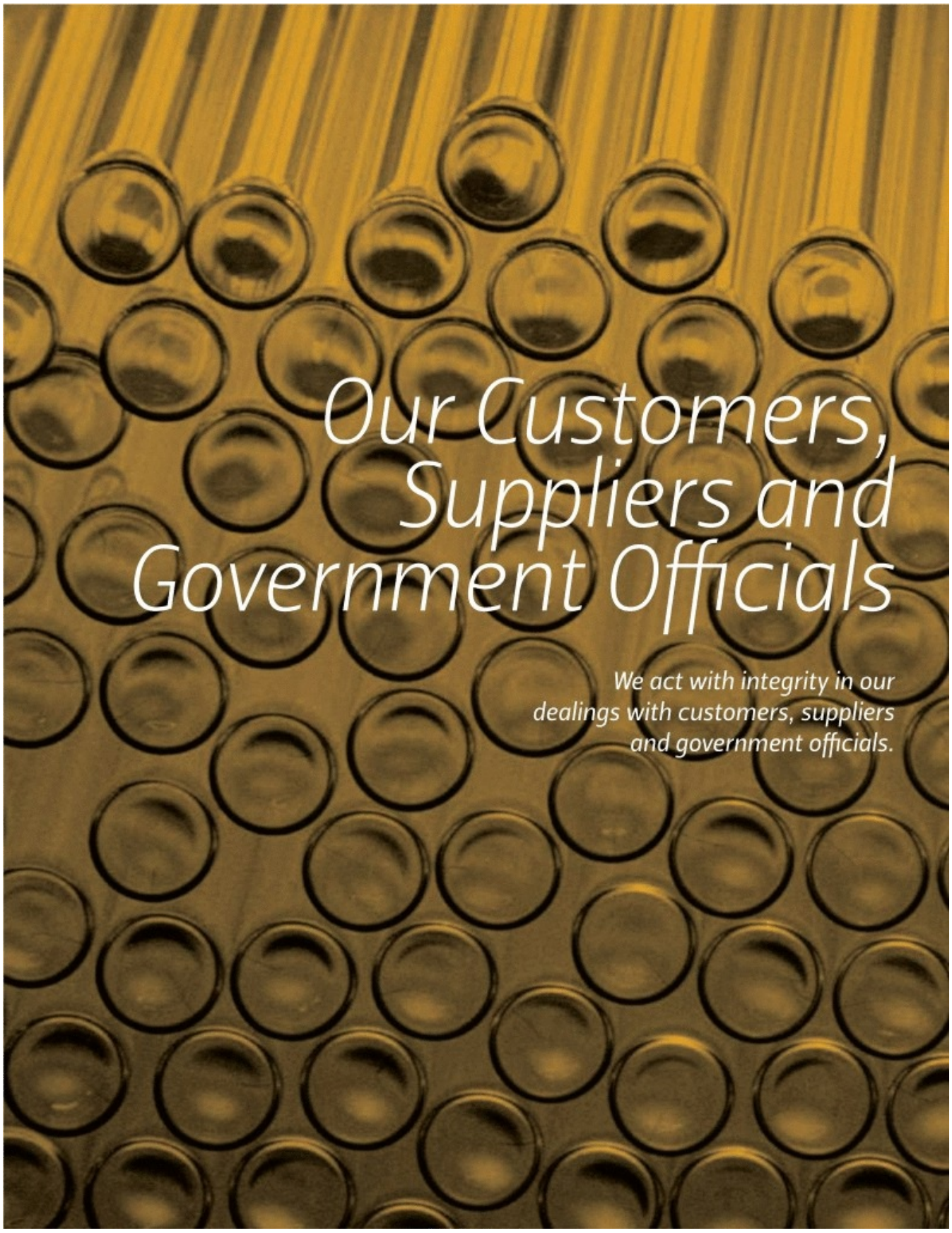
We operate in a complex and dynamic regulatory environment. Our facilities and activities are routinely inspected by healthcare and other regulators around the world. At all times, Endo cooperates with regulatory authorities. Effective engagement with regulators is critical to our reputation and our ability to deliver safe, effective and high quality products. In the event of a non-routine request for information or a facility visit, the Legal Department must be notified immediately. The Legal Department represents the Company on all legal matters and determines the appropriate information to be provided and will facilitate our cooperation with investigative authorities.

The Endo Way

- Cooperate with and be courteous to government inspectors and coordinate with our quality, safety and regulatory experts in response to regulatory inspections and requests
- Always provide regulators with honest, accurate, responsive and timely information
- Be familiar with your site's procedures for complying with a request to access the premises
- Contact the Legal Department immediately in the event of a non-routine or legal inquiry, such as a subpoena

How should I respond to an inspector's question about a process with which I am not familiar?

Be truthful and upfront. It is okay to state, "I don't have an answer" and tell the inspector that you will get the answer as soon as possible. Never guess, provide incomplete information or answer questions that you do not fully understand.



Our Customers, Suppliers and Government Officials

We act with integrity in our dealings with customers, suppliers and government officials.

Our Customers, Suppliers and Government Officials

Endo interacts with many types of individuals and entities including healthcare professionals, hospitals, governments, regulatory authorities, business partners, customers, suppliers and vendors. These interactions may arise in our sales and marketing, research and development, and manufacturing operations, as well as our import/export activities. In all business dealings, Endo will be fair and honest and will comply with applicable law and Company policies.

The Endo Way

- Adhere to competition and antitrust laws in the countries where we operate
- Comply with anti-bribery laws and do not offer or make illegal payments to government officials or business partners either directly or indirectly through intermediaries
- Provide transparent and accurate pricing information to governments, private payors and healthcare providers
- Gather competitive intelligence in an ethical and lawful manner
- Conduct political activity responsibly and in compliance with applicable law
- Follow global trade laws

Competition and Antitrust

Many countries have fair competition laws. These laws generally prohibit anti-competitive practices, such as price-fixing, boycotting suppliers or customers and the exchange of information that may harm competition.

Mergers, acquisitions and other types of transactions may require prior review or even clearance. These laws are complex and vary by country, so it is critical that you consult with the Legal Department.

The Endo Way

- Do not discuss, exchange information or enter into agreements with competitors about prices, strategic plans, terms or conditions of sale, production or distribution, allocation of products, territories, markets or customers, and do not use third parties as conduits for any such discussions, information exchanges or agreements
- Do not discuss or plan joint behavior (such as boycotts) towards customers, suppliers or competitors
- Do not make false or disparaging comments about competitors or their products or steal or misuse competitor trade secrets
- Do not manipulate a competitive bidding process

I am attending a local industry association meeting and several competitors are discussing their marketing and pricing strategies. What should I do?

Although industry meetings have legitimate purposes, they create risks for anti-competitive discussions. A group of competitors discussing issues of mutual concern could cross a line into an anti-competitive topic. If you find yourself in a situation where a topic seems inappropriate, leave the discussion immediately and make it clear to those present that you are leaving due to the nature of the conversation. You should also report the issue to your legal contact as soon as possible.

Anti-Corruption and Anti-Bribery

As regulators, payors 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. Most countries forbid making, offering or promising anything of value either directly or indirectly to a government official when the exchange is intended to influence an official act or a decision to obtain or retain an unfair business advantage. The U.S. Foreign Corrupt Practices Act ("FCPA") and similar laws in other countries govern our interactions with government officials.

Many countries also have laws aimed at prohibiting commercial bribery. The U.S. Federal Anti-Kickback statute prohibits inducing someone to recommend or purchase a healthcare product or service covered by the U.S. federal healthcare program. The intent of this law is to prohibit the impermissible influence of money or things of value in the selection of products or services that are reimbursed by the U.S. federal healthcare program.

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.

The Endo Way

- Do not make, offer or promise anything of value, including cash, services, gifts, entertainment or other business courtesies, in an attempt to influence a person's actions, obtain a regulatory advantage, influence formulary status or enhance Endo's commercial interests
- Business courtesies and gifts offered or received must be of modest value by local standards and may only be offered or received under circumstances that comply with Company policies and local law and industry codes
- Be aware that in countries with nationalized or public healthcare systems, healthcare professionals may be considered government officials
- Adhere to Company policies when interacting with government officials and be conscious of whether you are interacting directly or indirectly (such as through a distributor or other third party) with government officials
- Maintain your knowledge and complete training on Company policies and global and local anti-bribery laws

In my country, it is customary to provide a healthcare provider who uses one of our new products with a scientific incentive payment. Are such payments permissible under our Code of Conduct?

No. Any form of payment used to exert improper influence over healthcare professionals is prohibited, regardless of the customary practices in the country. In many countries, healthcare professionals are considered government officials and the payment could violate the FCPA or similar laws. Remember, when Endo's standards differ from local requirements always follow the higher standards.

Pricing and Billing Information

The procedures for obtaining payments and reimbursements from government and private insurers are complex.

We have a legal and ethical responsibility to provide transparent pricing information to governments, private payors and healthcare providers. The submission of inaccurate pricing information or fraudulent claims to a government could subject our Company to substantial fines and penalties.

The Endo Way

- Always provide accurate and complete information to government and private payors
- Adhere to Company policies on obtaining approval for, documenting and communicating lawful discounts, rebates or administrative fees
- Utilize accurate and complete information about billing, coverage, reimbursement and coding that adheres to local law and industry codes

I am hiring a researcher from a competitor. What questions may I ask about his or her prior employer?

Never ask a former employee of a competitor about any information that the person is under a legal obligation not to reveal. This would include trade secrets and other confidential information. Consult with the Legal Department about necessary precautions to avoid improperly soliciting such information.

Competitive Intelligence

Endo employees are encouraged to appropriately collect, share and use information about our competitors ("competitive intelligence"). However, just as we value our own non-public information, we respect the non-public nature of certain information about our competitors. We use only ethical and legal means to gather competitive intelligence.

It is always acceptable to gather competitive intelligence through publicly available information. Publicly available filings, presentations, news, journal articles and publications are legitimate sources of competitive intelligence. You may also ask third parties about competitors or accept competitive intelligence offered by third parties as long as there is no reason to believe the third party is under a contractual or legal obligation to not disclose the information or has gathered the information illegally or unethically.

The Endo Way

- Never attempt to or ask a third party to acquire information through unethical or unlawful means, such as misrepresentation, deception, theft, spying, bribery or by breaching a nondisclosure agreement
- If there is any indication that information you obtained was not lawfully or ethically received or gathered, refuse to accept it
- If you receive competitive intelligence anonymously or information that is marked confidential, do not review it and contact the Legal Department immediately

Political Activities and Political Donations

Endo educates policymakers through well-informed policy positions on issues that impact our business. Our participation in the political process is appropriate, ethical and adheres to applicable laws.

Endo recognizes and encourages the right of our employees to participate in the political process as individuals. However, you may only participate on your own time and at your own expense. Company funds, facilities or assets may not be used for personal political activities.

Many countries regulate the political activities of corporations. You should consult with Government Affairs regarding potential political activities. In the U.S., gifts of any value including meals or products should not be provided to Members of the U.S. Congress, their staffs or state and other government officials. Only certain individuals in Government Affairs may engage in lobbying activities on behalf of the Company.

Although prohibited under U.S. law from making payments to political parties, candidates or organizations, Endo is permitted to and has established a Political Action Committee ("Endo PAC") in the U.S. Contributions to the Endo PAC are entirely voluntary. No employee will be favored or disfavored based on his or her contributions.

The Endo Way

- No corporate contributions for a candidate for any office should be made by or on behalf of Endo outside of the Government Affairs Department
- Consult with Government Affairs prior to contacting public officials about U.S. and international restrictions on corporate political activities
- Do not use Endo funds or other assets, such as telephones, email accounts, conference rooms or stationary to assist a candidate, public official or political committee
- In personal civic affairs, clearly indicate that your views and actions are your own, not Endo's

A friend is running for local office and I would like to help him with his campaign. Is this allowed?

Yes. Your personal political activities are your own—not Endo's. Just make sure not to use Company resources including Company time, email or the Company's name to advance the campaign.

Trade Restrictions

Most countries regulate the flow of materials, information, services and funds into and out of their territories. We must comply with licensing requirements, boycotts, embargoes and other trade restrictions that have been approved by recognized national and international authorities. Such requirements may relate to, among other items, chemicals, biological materials, equipment, finished products and data/technology.

Endo will not engage in business with countries or parties subject to such trade sanctions unless lawful and properly authorized. We also comply with export licensing, clearance requirements and customs laws for the countries in which we do business. Endo will provide accurate and truthful information about our products and other items (such as pharmaceutical ingredients) to customs and other relevant authorities. Endo will not cooperate with any requests to participate in international boycotts as prohibited by law.

The Endo Way

- Maintain and complete accurate import declarations and review the export classification of materials prior to export to determine if a special authorization is required
- Know your customer and supplier and screen your transactions against all applicable rules that prohibit improperly dealing with sanctioned countries, persons or entities
- Do not cooperate with illegal restrictive trade practice or boycotts
- If your responsibilities involve international dealings, maintain your knowledge of and compliance with current import/export controls, licensing requirements and trade restrictions which change frequently due to political and security threats

I am trying to clear a product through customs. The local customs agent is asking for an additional signature to satisfy local requirements. I know it is customary to offer something to "speed things up." Time is of the essence. If local customs is not cleared quickly, patients may be adversely impacted by a supply shortage. What should I do?

First, understand the current import/export requirements for the country involved. Determine if further authorizations are in fact required by local law. Never provide gratuities to any officials to facilitate preferential treatment, regardless of the unwritten law of the land. Seek the advice of your manager or the Legal Department to identify legally acceptable ways to secure a timely release of our product.

Our Workplace and Our Communities

Our workplace environment and commitment to our communities reflects our values. Through our giving, we also strive to improve treatment outcomes.

Our Workplace and Our Communities

Endo seeks to create a productive work environment that reflects our values and attracts diverse and talented employees. This involves striving to maintain a safe workplace and to preserve our environment and always adhering to environmental and safety laws. As a Company, we strive to improve treatment outcomes and are committed to appropriate partnerships with third parties that further these goals. We also support the global and local communities where we work and live.

The Endo Way

- Maintain fair employment practices that comply with applicable law and foster a culture of respect, trust and integrity that facilitates productivity, collaboration and values diversity
- Protect the health and safety of our employees in accordance with Company policy and law
- Strive to act in an environmentally responsible way and comply with environmental laws
- Positively impact our communities through active engagement and support

Our Work Environment

Each of us is responsible for maintaining a work environment that is free from unlawful harassment in any form and recognizes and values a diverse workforce. Our employees should exhibit the highest standards of professionalism and integrity. Any behavior that constitutes unlawful harassment or discrimination will not be permitted. Endo recruits, hires, trains and promotes our employees without regard to their race, color, religion, gender, age, national origin, citizenship, marital status, sexual orientation, gender identity, genetic information, disability, veteran status or other protected characteristic.

The Endo Way

- Discourage and report comments or physical acts that are inappropriate, offensive or derogatory to others
- Jokes, slurs and other remarks about characteristics that are protected by law, or that are of a sexual nature, are not appropriate
- Remarks or physical conduct that interfere with another person's work or creates an intimidating, hostile or offensive work environment are not tolerated
- Follow Company policies and applicable laws prohibiting unlawful discrimination

One of my colleagues makes seemingly innocent and complimentary comments about the appearance of a peer. Is it appropriate?

Frequent comments may rise to the level of creating a hostile work environment. An occasional general comment such as "I like your new haircut" is generally acceptable. Much depends on the specific nature of the comments, their frequency and the overall environment. If in doubt about the appropriateness of a comment, do not make it. Intimidating, hostile or offensive comments should be reported to your manager, Human Resources, Legal or the Ethics Hotline.

Protecting Employee Safety and the Environment

Endo employees are one of our most valuable assets. We have a responsibility to each other to maintain the safety and security of our work areas. Endo is committed to maintaining a work environment free from the influence of any substance that could impair our ability to safely and professionally execute our job responsibilities. Violence in the workplace will not be tolerated.

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

The Endo Way

- Participate in safety training and adhere to Company safety and security policies
- Promptly report safety concerns or threatening or violent behavior
- Never use alcohol, illegal drugs, controlled substances or medication in a way that might harm your ability to perform Endo business safely and successfully
- Selling, purchasing, possessing or using any illegal drug on Endo property or while conducting Endo business is prohibited
- Do not engage in violent or physically threatening conduct while taking part in any work-related activity
- It is prohibited to possess firearms, weapons, fireworks or explosives on or near areas of Company property
- Comply with all applicable environmental laws and report any environment incidents
- Take appropriate measures to reduce or eliminate the creation of waste and conserve resources

Supporting the Community

Endo is committed to supporting initiatives that improve our communities, provide better access to care for patients and improve treatment outcomes. We support appropriate education for healthcare professionals and research that will advance scientific knowledge about our products and develop new products.

Our grants, donations and charitable contributions take the form of healthcare partnerships, community partnerships and disaster relief, as well as support for non-profits and global initiatives. We fund high-quality educationally-appropriate and timely medical education. Endo-supported education must provide fair, balanced and independent content to healthcare professionals and be delivered in accordance with applicable local law and relevant industry standards.

The Endo Way

- Support non-profit organizations that facilitate involvement with and assistance to our local communities
- Support disaster relief as well as non-profit and global initiatives in a manner that is consistent with our mission and policies
- Foster partnerships through the support of local or regional public health policy efforts to protect and improve the quality of care for patients
- Support medical education and clinical training to help advance improvements in patient care in Endo's areas of therapeutic interest consistent with industry standards and Company policies
- Support independent investigator sponsored research that may advance clinical care, medical and scientific knowledge about our products and lead to new medical therapies consistent with industry standards and Company policy

One of the physicians in my region has been telling me that he would like the opportunity to conduct an investigator sponsored study with one of our products. He doesn't know what that could be and he asked me to find out what the company has been looking into and might be inclined to approve. As a sales person, I am aware of our brand team's strategy and could easily give him some ideas. Should I do it?

No. Investigator sponsored research should be based on ideas originated by the investigator him/herself and in your role as a salesperson, your responsibility is only to direct the physician to an approved Endo grants portal for information.

Can an Endo employee provide input on the content of a Continuing Medical Education ("CME") event or program funded by an Endo grant?

No. All CME activities funded through Endo grants are independent and must not be influenced by Endo in any way.

Our Company and Our Shareholders

We are responsible for conducting our operations in the best interest of our Company and making ethical business decisions that create value for shareholders.

Our Company and Our Shareholders

Endo will operate in the best interests of the Company and our shareholders, be forthright about our operations and performance and exercise care in the use and protection of our assets and resources.

The Endo Way

- Avoid conflicts of interest
- Do not disclose inside information and never trade public securities based on inside information
- Protect patents, trademarks, trade secrets and other intellectual property and safeguard confidential information
- Respect privacy and appropriately safeguard personal information, including personal health information
- Maintain and retain accurate books and records consistent with applicable law and Company policy
- Maintain an effective system of controls over financial reporting
- Use Company resources and systems appropriately

Conflicts of Interest

Nothing you do in your professional life or during your free time should conflict with your responsibilities to Endo. A conflict of interest arises when the prospect of personal gain may improperly influence your ability to conduct Endo's business. Examples may include using your position for personal gain, outside employment interfering or competing with your Endo employment, referral of Endo business to a firm with which you have a personal relationship or soliciting or receiving gratuities from suppliers or vendors.

Endo deals with suppliers and others doing business with us in a fair and objective manner without favor or preference. A conflict of interest or potential conflict of interest may often be resolved or avoided if disclosed and approved. In other instances, disclosure may not be sufficient. It is important that you use available resources to discuss and resolve any potential conflicts of interest.

My neighbor who is a close personal friend owns a company that supplies certain materials to Endo. Is this a conflict of interest?

Although not explicitly prohibited, it would be appropriate to disclose this to your manager. If appropriate, your manager will work with the Legal Department and your compliance leader to find the best solution. In no way should you try to influence our business with your friend's company.

How do I understand if an offer of a meal or entertainment from a supplier is appropriate? I did not solicit the invitation, which I know would be impermissible.

You may accept infrequent and occasional meals and entertainment if the supplier attends and the costs are modest by local custom. Ordinary business meals and attendance at local sporting events are generally acceptable. An invitation to an out of town or a premium event would not be appropriate. Even a gift of modest value could create an appearance of a conflict of interest, such as if the supplier may be bidding on Endo business. If in doubt, discuss the issue with your business compliance leader or manager. It is always preferable to pay the fair market value of a meal or ticket to avoid any potential appearance of a conflict of interest.

The Endo Way

- Disclose to your manager, legal contact or compliance leader outside activities and employment relationships, financial interests or relationships that may present an actual or potential conflict
- Obtain approval from your legal contact or compliance leader before accepting an officer or director position with an outside business or serving on a non-profit board
- Do not seek or accept, directly or indirectly, any payments, fees, loans or services from any person or firm as a condition for their doing business with Endo
- Do not seek or solicit any gifts, entertainment or benefits from those doing business or seeking to do business with Endo
- Do not accept gifts, entertainment or benefits greater than modest value by local standards from those doing business or seeking to do business with Endo and avoid any perception of a potential conflict of interest
- Do not use or misuse Endo resources, intellectual property or facilities for personal gain
- Do not allow personal relationships to conflict with your Endo responsibilities
- Avoid hiring, promoting or directly supervising a family member or close friend

Insider Trading

Many countries have laws regarding insider trading. As an Endo employee, you may learn of inside information—information that is not known to the general public and that an average investor might consider important when deciding whether to buy, sell or hold securities. You may not disclose this information to others. No Endo employee may engage in any transaction in Endo or another company's securities while he or she is aware of inside information.

Illustrative examples of potentially inside information are information about a potential business acquisition, internal information about revenues, earnings or other aspects of financial performance that have not yet been publicly disclosed or that depart from what the market would expect based upon prior disclosures, important business developments (including research and development results, regulatory approvals or non-approvals of one of our products), the acquisition or loss of a major customer or an important transaction.

Certain employees, known as "restricted personnel" under our Insider Trading Policy, are more likely to have inside information and are prohibited from trading in any securities during "restricted periods." A "restricted period" generally begins two weeks prior to the end of each fiscal quarter or year and ends when the market opens on the third day after earnings are released for each fiscal quarter or year.

The Endo Way

- Adhere to Endo's Insider Trading Policy
- Never purchase or sell or direct anyone else to purchase or sell any type of security while you are aware of inside information about Endo or any other company
- Be familiar with Endo's "restricted periods" and whether you are "restricted personnel," subject to a restrictive trading period due to a heightened risk of you possessing inside information
- Do not directly or indirectly disclose ("tip") inside information to anyone, including family members and friends, even if you do not intend for the tipee to use the information to buy or sell securities
- Contact our Chief Financial Officer or Chief Legal Officer if you have any questions

I recently learned that Endo is actively negotiating a joint venture with a publicly-traded company that I have been researching as a potential investment. May I still purchase stock in this company?

No. Trading on material non-public information is illegal. The prohibition applies to trading in the stock of Endo or the other company, even if you have an unrelated reason for trading the stock.

Intellectual Property and Confidential Information

Some of our most valued assets are our intellectual property and confidential information. Protecting these assets

is critical to our growth. This includes our patents, trade secrets, trademarks, copyrights, know-how, data, processes, experience, customer information and technical and business knowledge. A few examples are sales and marketing databases, marketing

strategies and plans, pricing information, manufacturing techniques and research and technical data.

Every Endo employee must protect our intellectual property and maintain the secrecy of our confidential information. Even after employees leave Endo, they must continue to respect our intellectual property and not disclose confidential or proprietary information. Unauthorized use of the intellectual property or confidential information of others is also prohibited.

The Endo Way

- Identify and protect Endo intellectual property
- Respect valid patents, copyright materials and the intellectual property rights of others
- Consult with Endo's Intellectual Property legal counsel before soliciting, accepting or using confidential information or disclosing Endo's confidential information or permitting use of our intellectual property
- Understand your responsibilities regarding new inventions and ideas that you develop as an Endo employee
- Do not discuss confidential information in public places
- Do not use confidential information or intellectual property from other companies or persons, unless Endo has the legal right to such use

I overheard Endo employees discussing company business on a train. What should I do?

If you believe the information is sensitive or confidential, advise the parties they can be overheard and contact the Legal Department. Every Endo employee has a responsibility to protect confidential and proprietary information from inappropriate use or disclosure.

Privacy

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.

Many countries in which Endo operates have laws that govern how we treat personal information. Before engaging a vendor or other third party to assist with any handling or sharing of personal information, particularly personal information of patients, make sure to consult with Legal so that the appropriate safeguards can be put in place to comply with privacy laws in the United States and abroad. Always follow Endo's policies and processes for sharing personal information of employees, patients or others, and pay particular attention to policies regarding sharing that information with Endo's subsidiaries that operate outside the United States. Respect for the privacy of personal information earns the trust and confidence of patients, customers, shareholders and employees and we are committed to adhering to applicable privacy laws worldwide.

The Endo Way

- Avoid collecting, using or accessing personal information unless you have a legitimate business purpose and are authorized to obtain the information
- Collect the minimum necessary information and whenever possible do not collect information that identifies a specific person
- Do not share personal information with unauthorized individuals or entities
- Respect the privacy preferences of individuals about how their personal information may be used
- Third parties and agents to whom we legitimately disclose personal information should have policies and appropriate safeguards in place
- Take steps to reasonably ensure that personal information—particularly sensitive personal information such as health information—is appropriately secured in accordance with Company policies and applicable laws
- In the event of an actual or potential loss or unauthorized disclosure of personal information, immediately report the incident to the Ethics Hotline
- Comply with all Company policies and guidance documents regarding personal information and information security, as well as those related to use of Company resources and Company records and information management

One of our vendors who handles personal information on our behalf mentioned that they had a security problem with one of their data systems that includes personal information. What should I do?

Report this to the Ethics Hotline immediately. Endo will assess whether there may have been a security breach involving personal information and determine an appropriate response based on this assessment. Prior to initiating a relationship with a vendor who handles personal information on our behalf, steps should be taken to confirm that appropriate policies and safeguards are in place.

My manager asked me to ship my distributors double the amount of products typically sold to boost our quarterly sales figures. What should I do?

Do not compromise your integrity. The practice of knowingly selling more products than your distributors can sell is illegal. Raise this issue with your finance or compliance leader or your legal contact. You may also contact the Ethics Hotline.

Financial Integrity

To fulfill our commitment to our shareholders, the public and government agencies, our books and records must fairly represent in all material respects the financial condition, operational results and cash flows of the Company. Endo employees are responsible for being aware of and adhering to our system of internal financial controls and Company policies.

Our internal controls are designed to provide reasonable assurance regarding the effectiveness and efficiency of our operations, the reliability of our financial reporting, and our compliance with applicable laws and regulations. You should always assist in taking corrective actions in the case of a control failure, reporting any policies or procedures that are not being followed and identifying any control weaknesses.

The Endo Way

- Prepare and maintain accurate and complete Company records
- Only sign records you believe to be accurate and complete after appropriate review
- Financial transactions must be appropriately authorized, be recorded in the accounting period in which they were incurred and be in the appropriate accounts with supporting documentation
- Be transparent and do not withhold information from our independent or internal auditors
- Never falsify records, misrepresent facts or circumvent our controls
- Always exercise great care when handling financial transactions and reporting for the Company to ensure the accuracy of Company accounts, and to protect the security of Company funds

Use of Company Systems and Resources

Each of us is entrusted with the proper use of Company systems and resources. Although the incidental and occasional personal use of our systems subject to certain restrictions is permitted, these systems and resources should be used for legitimate business purposes. Except where required by local law, the privacy of information stored on or sent to or from Company systems is not guaranteed. Endo may inspect your files or other information contained on its servers or other property, including devices, at any time and without prior notice.

The Endo Way

- Do not use any Endo system or device to send or access inappropriate, harassing, discriminatory, sexually explicit or defamatory material
- Safeguard your system passwords and do not share them except for a valid business reason (such as technical support) after which they should be changed
- Do not record communications without proper authorization and only as otherwise permitted under local law
- Do not leave Endo computers or devices unattended in places where they could be accessed or misused by unauthorized persons
- Treat all computer data as confidential

Company Records and Information Management

Endo employees must accurately create, maintain, store and, when appropriate and in compliance with policy, destroy Company records in a manner that protects the integrity of the information. Effective records management facilitates sound decision-making, promotes operational efficiency and is integral to addressing our legal, financial, regulatory and contractual obligations.

Company records are viewed broadly and include records in all mediums such as paper (including handwritten notes), audio or video recordings and computer-based information, including emails and electronic files. You should comply with Company records management policies and retention schedules. Requests by third parties (such as governmental agencies), lawsuits or other inquiries may necessitate the need to hold records beyond normal retention schedules. It is Endo policy to preserve any records relevant to a "Legal Hold" or any other "Hold Order" issued.

The Endo Way

- Be knowledgeable of how Company records management policies apply to your job responsibilities
- Retain records for the time period specified by applicable laws, Company policies and retention schedules
- If you receive a "Hold Order," take special care to retain all documents or other records relevant to the "Hold Order"
- Comply with all Endo policies and guidance documents regarding records management, including Company policies and procedures regarding information security
- Timely complete all training requirements concerning Company records, information management, data integrity, privacy and information security
- Never conceal, alter or destroy records relating to an imminent or ongoing investigation, lawsuit or inquiry
- Never leave Company documents unattended in public places and report any accidental loss or destruction of documents

Can I check my personal email from work?

Generally, you may check your personal email or access the internet using Company systems for limited personal purposes. You are still subject to Company policies. As an example, it would be inappropriate to access or download inappropriate content from the internet, such as sexually explicit, discriminatory or otherwise disruptive or offensive material. Personal use of Company systems should be occasional and not impact your job performance. Endo may monitor and inspect your internet usage at any time.

Corporate Affairs and Investor and Media Relations

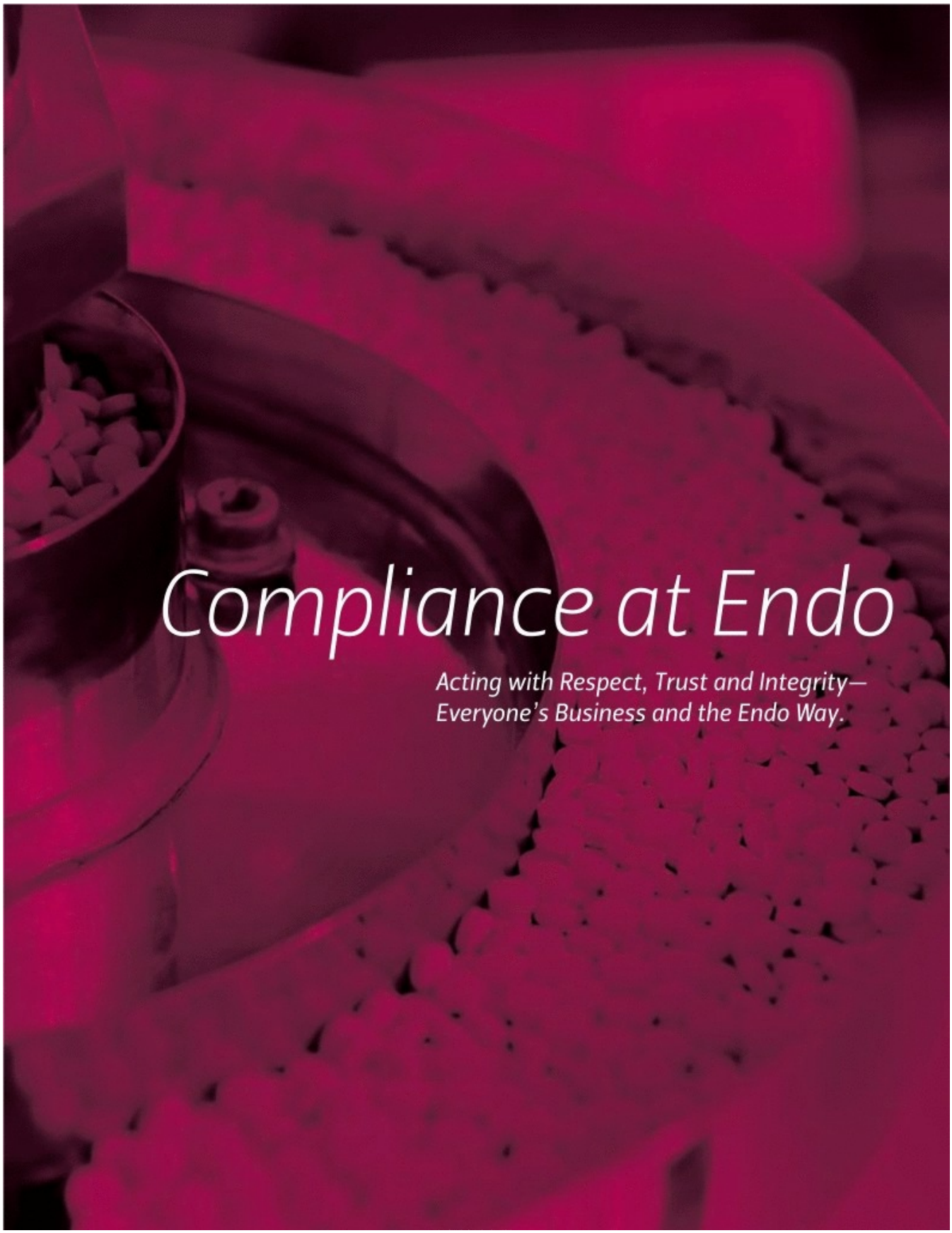
Endo is committed to delivering accurate, reliable, timely and fact based information to financial analysts, investors, the media and members of the public. To facilitate the appropriate provision of information, outside inquiries related to Endo or our business units should be directed to Corporate Affairs. If an Endo employee is contacted by a representative of a government agency, an attorney or a representative of an attorney seeking an interview or making a non-routine request for documents, the Legal Department should be contacted immediately. Endo employees should not make statements to the media about the Company's business without appropriate authorization. Any media inquiries should be immediately sent to Corporate Affairs.

The Endo Way

- Do not provide any information about Endo or its businesses to outside sources, including the media, financial analysts, governmental officials, attorneys or their representatives without appropriate authorization
- If you are asked for information about current or former employees, refer the request to Human Resources
- If contacted by a government agency related to an inquiry, politely inform the government representative that as a matter of Company policy you are required to refrain from providing information until you have contacted the Legal Department

I have been asked to speak at a conference about my areas of expertise at Endo. Can I do this?

Invitations to speak on your area of expertise as a representative of the Company should not be accepted without prior approval from your manager and the Corporate Affairs Department. In the event that your presentation may reveal confidential information or impact our ability to protect our intellectual property, you should consult with the Legal Department.


Compliance at Endo
Acting with Respect, Trust and Integrity—
Everyone's Business and the Endo Way.

Compliance at Endo

Ethics Hotline
800-305-1563
Visit
www.endo.ethicspoint.com
to report a concern
or access toll-free
international numbers

Our Compliance Program

The Compliance and Business Practices Department oversees our Company's compliance program which is founded on our Company's values and its commitment to ethics and compliance. The Department maintains an effective company-wide compliance program by establishing clear rules of business conduct, educating and training our employees and conducting ongoing monitoring to maintain a program that is operating as intended and to enhance its effectiveness.

The Department also strives to establish relationships founded on trust, collaboration and mutual respect that are the basis for a proactive and sustainable approach to ethics and compliance.

Where can I get further information on Endo's Compliance Program?

Further information is available at the Corporate Compliance and Business Practices Department's intranet site at http://at.endo.com/ourbusiness/departments/corpcompliance/Pages/Default.aspx. This site contains contact information for your business compliance leaders and information about Company compliance policies and procedures as well as educational and training efforts.

The Endo Way

- Oversight by our Board of Directors through a compliance sub-committee that receives at least quarterly updates on Endo's compliance program
- Our Chief Compliance Officer reports directly to our Chief Executive Officer and may also report compliance matters directly to the Board of Directors
- Our Global and U.S. Compliance Committees, both of which are comprised of members of the Executive Leadership Team and other senior leaders, oversee, assess and enhance our compliance program and supports Endo's strategic approach to compliance both in the U.S. branded pharmaceuticals business and throughout all of Endo's businesses worldwide
- Operate in accordance with written standards, such as this Code of Conduct and business unit compliance policies
- Promote and support ongoing education and training of our employees on this Code, Company policies and applicable laws
- Oversee the monitoring and auditing of our compliance with Company policies and procedures
- Conduct fair, objective and timely investigations of potential compliance violations
- Respond appropriately to violations and adopt corrective and preventative measures, where appropriate

The Endo Way

- Act with honesty, fairness, integrity and personal accountability to protect our reputation
- Never compromise your integrity for the sake of "making the numbers" or due to pressure from a supervisor
- Respect fellow staff, government officials, business partners, competitors, customers and patients
- Know and follow the rules and seek guidance
- Sustain a culture where ethical conduct is expected, recognized and valued
- Report known or suspected violations of this Code
- Cooperate with investigations—always be forthcoming and tell the truth
- No form of retaliation or intimidation against an employee who makes a good-faith report of a suspected violation or participates in good faith in any investigation of a suspected violation will be tolerated

Acting with Respect, Trust and Integrity

The Endo Way

Endo
www.endo.com
ENG-AUG2018

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

The following is a list of significant subsidiaries of the Company as of December 31, 2018.

Subsidiary	Jurisdiction of Incorporation or Organization	Ownership by Endo International plc
Actient Therapeutics, LLC	Delaware	Indirect
Anchen Pharmaceuticals 2, Inc.	Delaware	Indirect
Astora Women's Health, LLC	Delaware	Indirect
Auxilium Pharmaceuticals, LLC	Delaware	Indirect
Endo Bermuda Finance Limited	Bermuda	Indirect
Endo DAC	Ireland	Direct
Endo Finance II Limited	Ireland	Indirect
Endo Finance IV Limited	Ireland	Indirect
Endo Finance Limited	Ireland	Indirect
Endo Finance LLC	Delaware	Indirect
Endo Finance Operations LLC	Delaware	Indirect
Endo Global Biologics Limited	Ireland	Indirect
Endo Global Ventures	Bermuda	Indirect
Endo Health Solutions Inc.	Delaware	Indirect
Endo Ireland Finance Limited	Ireland	Indirect
Endo Luxembourg Finance Company I S.a r.l.	Luxembourg	Indirect
Endo Luxembourg Finance Company II S.a r.l.	Luxembourg	Indirect
Endo Luxembourg Holding Company S.a r.l.	Luxembourg	Indirect
Endo Management Limited	Ireland	Indirect
Endo Par Innovation Company, LLC	Delaware	Indirect
Endo Pharmaceuticals Inc.	Delaware	Indirect
Endo TopFin Limited	Ireland	Indirect
Endo U.S. Inc.	Delaware	Indirect
Endo US Holdings Luxembourg I S.a r.l.	Luxembourg	Indirect
Endo US Holdings Luxembourg II S.a r.l.	Luxembourg	Indirect
Endo Ventures Limited	Ireland	Indirect
Generics Bidco I, LLC (doing business as Par Pharmaceutical)	Delaware	Indirect
Generics International (US Parent), Inc.	Delaware	Indirect
Generics International (US) 2, Inc.	Delaware	Indirect
Hawk Acquisition Ireland Limited	Ireland	Indirect
JHP Group Holdings 2, Inc.	Delaware	Indirect
JHP Group Holdings, LLC	Delaware	Indirect
Luxembourg Endo Specialty Pharmaceuticals Holding I S.a r.l.	Luxembourg	Indirect
Luxembourg Endo Specialty Pharmaceuticals Holding II S.a r.l.	Luxembourg	Indirect
Paladin Labs Canadian Holding Inc.	Canada	Indirect
Paladin Labs Inc.	Canada	Indirect
Par Pharmaceutical 2, Inc.	Delaware	Indirect
Par Pharmaceutical Companies, Inc.	Delaware	Indirect
Par Pharmaceutical Holdings, Inc.	Delaware	Indirect
Par Pharmaceutical, Inc. (doing business as Par Pharmaceutical)	New York	Indirect
Par Sterile Products, LLC	Delaware	Indirect
Par Two, Inc.	Delaware	Indirect
Vintage Pharmaceuticals, LLC	Delaware	Indirect

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-194253, No. 333-204958, No. 333-219806 and No. 333-226677) and Form S-3 (No. 333-226676) of Endo International plc of our report dated February 28, 2019 relating to the financial statements and financial statement schedule and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania
February 28, 2019

Exhibit 24.1

POWER OF ATTORNEY

Each of the undersigned, hereby constitutes and appoints each of Paul V. Campanelli, Blaise Coleman, Matthew J. Maletta and Yoon Ah Oh to be his or her true and lawful attorneys-in-fact and agents, with full power of each to act alone, and to sign for the undersigned and in each of their respective names in any and all capacities stated below, this Annual Report on Form 10-K (and any amendments hereto) and to file the same, with exhibits hereto and thereto and other documents in connection herewith and therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Power of Attorney has been signed by the following persons in the capacities and on the dates indicated.

Signature	**Title**	**Date**
/s/ Roger H. Kimmel Roger H. Kimmel	Chairman and Director	February 14, 2019
/s/ Shane M. Cooke Shane M. Cooke	Director	February 14, 2019
/s/ Nancy J. Hutson, Ph.D. Nancy J. Hutson, Ph.D.	Director	February 14, 2019
/s/ Michael Hyatt Michael Hyatt	Director	February 14, 2019
/s/ Sharad S. Mansukani, M.D. Sharad S. Mansukani, M.D.	Director	February 14, 2019
/s/ William P. Montague William P. Montague	Director	February 14, 2019
/s/ Todd B. Sisitsky Todd B. Sisitsky	Director	February 14, 2019

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Paul V. Campanelli, certify that:

1. I have reviewed this annual report on Form 10-K of Endo International plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's Board of Directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/S/ PAUL V. CAMPANELLI

Paul V. Campanelli

President and Chief Executive Officer
(Principal Executive Officer)

Date: February 28, 2019

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Blaise Coleman, certify that:

1. I have reviewed this annual report on Form 10-K of Endo International plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's Board of Directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/S/ BLAISE COLEMAN

Blaise Coleman

Executive Vice President, Chief Financial Officer
(Principal Financial Officer)

Date: February 28, 2019

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul V. Campanelli, as President and Chief Executive Officer of Endo International plc (the Company), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Annual Report on Form 10-K of the Company for the annual period ended December 31, 2018 (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/S/ PAUL V. CAMPANELLI

Name: Paul V. Campanelli

Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: February 28, 2019

A signed original of this written statement required by Section 906 has been provided to, and will be retained by, Endo International plc and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Blaise Coleman, as Chief Financial Officer of Endo International plc (the Company), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Annual Report on Form 10-K of the Company for the annual period ended December 31, 2018 (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/S/ BLAISE COLEMAN

Name: Blaise Coleman

Title: Executive Vice President, Chief Financial Officer
(Principal Financial Officer)

Date: February 28, 2019

A signed original of this written statement required by Section 906 has been provided to, and will be retained by, Endo International plc and furnished to the Securities and Exchange Commission or its staff upon request.